UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

In re Neurontin Marketing and Sales Litigation	**)**	**MDL Docket No. 04-MDL-1629**
	)	**Case No. 1:04-cv-12625-PBS**

MOTION FOR APPOINTMENT OF TENNESSEE LEAD COUNSEL

NOW INTO COURT comes Bauda Vauda Lee Sutton, Plaintiff in a consumer class action in the United States District Court for the Eastern District of Tennessee against the Defendants titled *Sutton v. Pfizer, Inc., et al.*, E.D. TN, No. 2:04-CV-337, by and through counsel, and respectfully moves this Court for appointment of Gordon Ball, counsel for Ms. Sutton, as Tennessee Lead Counsel and a member of the Executive Committee for Plaintiffs in this action. This motion is based upon the resume of Gordon Ball (Exhibit A) and the accompanying Memorandum of Law.

In further support thereof, Bauda Vauda Lee Sutton states as follows:

1. Ms. Sutton is an individual who resides in Tennessee and is a member of the proposed class in this multi-district litigation, as well as the named plaintiff and representative of a proposed class of similarly situated Tennessee residents in her consumer class action filed on August 11, 2004 in the Circuit Court for Cocke County, Tennessee (attached as Exhibit B). Ms. Sutton's case was removed to the United States District Court for the Eastern District of Tennessee on September 16, 2004 (Exhibit C).

The District Court stayed Ms. Sutton's Tennessee action on November 16, 2004 (Exhibit D).

2. On October 26, 2004, the Judicial Panel on Multidistrict Litigation transferred 23 civil actions in this matter to the Honorable Patti B. Saris of this Court for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Ms. Sutton's Tennessee action was transferred to this MDL Court on December 7, 2004 (Exhibit E).

3. Counsel for Ms. Sutton, Gordon Ball, should be appointed Tennessee lead counsel and a member of the Executive Committee for Plaintiffs to protect the interests of Tennessee consumers. Mr. Ball is the most qualified, competent and experienced counsel for representing Tennessee consumers and for formulating and presenting positions on Tennessee substantive and procedural issues during the litigation. His experience and qualifications are fully detailed in Exhibit A to this Motion. Mr. Ball is qualified to present written and oral arguments and suggestions to the court, to work with opposing counsel and other states' lead counsel in developing and implementing a litigation plan, to initiate and organize discovery requests and responses, to conduct the principal examination of deponents, to employ experts, to arrange for support services, and to ensure that schedules are met. Mr. Ball will fairly and equitably represent the interests of Tennessee consumers, and will assess a reasonable charge for services.

4. Counsel for Ms. Sutton, Gordon Ball, fully understands that the responsibilities of Tennessee Lead Counsel and a member of the Executive Committee for Plaintiffs in this litigation would extend beyond the resolution of Ms. Sutton's involvement and include responsibilities to this Court and include an obligation to act

fairly, efficiently, and economically in the interests of all parties and their counsel. Mr. Ball also understands that serving as Tennessee Lead Counsel and a member of the Executive Committee for Plaintiffs will include an obligation to keep other attorneys representing class members advised of the progress of the litigation and to consult them about decisions significantly affecting their clients. Mr. Ball will not bind the group without specific authority, nor will he, without court authorization, allow settlement discussions to interfere with his responsibility to move the litigation to trial on schedule.

5. The Tennessee complaint filed by Ms. Sutton alleges that Defendants' conduct is in violation of specific and unique Tennessee antitrust, consumer protection, and common laws. Her complaint seeks full consideration damages, actual damages, treble damages, and restitution individually for Tennessee indirect purchasers on a class-wide basis.

6. Under Rule 23(c)(4)(A) of the Federal Rules of Civil Procedure, a class or sub-class may be certified for only certain issues or claims in the litigation. At the appropriate time, Ms. Sutton and her counsel will move this court to certify a class or sub-class of Tennessee consumers in this litigation. Such a certification will enable the Court to achieve further economies of class action treatment for the Tennessee class members, who assert specific and unique provisions of Tennessee law.

7. Appointment of Ms. Sutton's counsel, Gordon Ball, as Tennessee lead counsel and a member of the Executive Committee for Plaintiffs in this action would avoid unnecessary duplication of efforts, control fees and expenses, and achieve efficiency and economy without jeopardizing fairness to Tennessee consumers and to the other parties in the litigation.

Respectfully submitted, this the 7th day of January, 2005.

__/s/___//Gordon Ball//_____
Gordon Ball
Ball & Scott
550 W. Main Avenue, Suite 750
Knoxville, TN 37902

Attorney for Bauda Vauda Lee Sutton

CERTIFICATE OF SERVICE

I, Gordon Ball, do hereby certify that a copy of the foregoing has been sent via U.S. Mail, sufficient postage prepaid, or through the United States District Court, District of Massachusetts CM/ECF electronic filing system, to the following:

[see attached service list]

This 7th day of January, 2005.

___/s/_//Gordon Ball//_____
Gordon Ball

Legal Resume of
Gordon Ball

Focusing on Consumer and Antitrust Class Actions

Suite 750, 550 Main Avenue
Knoxville, Tennessee 37902

Biography

Gordon Ball is a licensed Tennessee attorney whose practice focuses on consumer rights and antitrust class actions. Mr. Ball was born in Cosby, Tennessee. He graduated from East Tennessee State University with a Bachelor of Science degree in 1970, and graduated from the Cecil C. Humphreys School of Law at Memphis State University in 1974. Mr. Ball entered the private practice of law the following year.

Mr. Ball has been admitted to or appeared before federal and state courts in Tennessee, Alabama, Arizona, California, Florida, Georgia, Indiana, Illinois, Kansas, Kentucky, Maryland, Michigan, New Mexico, North Carolina, North Dakota, Oklahoma, South Dakota, West Virginia, and the District of Columbia.

In the late 1970's, Mr. Ball served as an Assistant United States District Attorney for the Eastern District of Tennessee. In 1977, he served as a delegate to the Tennessee Constitutional Convention. For several years after he returned to private practice, he specialized in the defense of "white-collar" federal prosecutions. In 1981, Mr. Ball was lead counsel in the case of *United States v. Sisk, et al* (aka, the "Pardons and Paroles" cases). His client was acquitted after a six-week trial. In 1986-87, Mr. Ball was co-lead counsel in the federal bank fraud prosecution of brothers Jake and C.H. Butcher, Jr., who had created a banking empire (United American Bank and C & C Bank) in East Tennessee. In *U.S. v. C.H. Butcher, et al.*, Mr. Ball was the only defense attorney to secure two "not guilty" jury verdicts.

Mr. Ball first became involved in major class action litigation in 1988, with *Shults v.*

Champion International Corporation. Mr. Ball and his co-counsel represented approximately 2600 landowners against a paper company who had polluted the Pigeon River for nearly eighty years. Mr. Ball and his co-counsel litigated against one of the country's largest law firms and were successful in recovering $6.5 million for the landowners.

For over fifteen years, Mr. Ball has been a pioneer in plaintiff's class action lawsuits on behalf of victims of abuse by powerful corporations. Mr. Ball has a long record of successful litigation on behalf of both individuals and classes, particularly in cases involving antitrust violations such as monopolization and price-fixing. Mr. Ball's aggregate multi-billion dollar recoveries have included cases against oil companies, telecommunications companies, health care companies, insurance companies, pharmaceutical companies, banks, auto manufacturers, record manufacturers, paper manufacturers, vitamin makers, boat manufacturers, stucco manufacturers, and supermarket chains. Mr. Ball and co-counsel are currently engaged in courtroom antitrust and consumer rights cases against credit card companies, electronics manufacturers, cigarette manufacturers and many others.

Mr. Ball has won a national reputation for fighting on behalf of American consumers by achieving recoveries in cases that other law firms did not want to handle. Several of the groundbreaking cases that Mr. Ball and his co-counsel have litigated have resulted in landmark decisions on previously untried or unsettled issues involving price-fixing and consumer rights.

An Experienced Class Action Litigation Firm

A lone consumer is often powerless against a powerful corporation. By creating a group or class, individuals can join together enhance their ability to assert their rights and challenge corporations who often have larger resources. As the premier class action law firm in Tennessee--and one of the premier class action firms in the South—Ball & Scott, and Mr. Ball in particular,

specialize in cases concerning Antitrust Actions, Consumer Protection & Product Liability, and Heathcare Fraud. Mr. Ball has been involved as lead or co-counsel in dozens of class actions which have resulted in billions of dollars in recoveries for consumers. Mr. Ball has represented (or is currently representing) consumers in the following class actions:

1. *Stinnett v. BellSouth Telecommunications*
($45,000,000.00 settlement);

2. *Land v. United Tel. - Southeast*
($5,000,000.00 settlement);

3. *In re Travel Agency Com'n Antitrust Litig.*
($70,000,000.00 settlement);

4. *Lowe v. Johnson City Medical Center Hospital*
($1,500,000.00 settlement);

5. *Shelton v. Blue Cross and Blue Shield of Tennessee*
($4,000,000.00 settlement);

6. *Nabors v. General Motors*
(General Motors nationwide settlement approved in Louisiana with settlement benefit to 6 million owners of GM vehicles);

7. *Cox, et al v. Shell Oil Co.*
($950,000,000.00 settlement)(product defect)
(Largest property damage settlement in U.S. history);

8. *Blake v. Abbott Laboratories, Inc.*
($62,000,000.00 settlement) (price-fixing of infant formula);

9. *Patrick v. Liberty Health Care Corp.*
($245,000.00 settlement) (unpaid sick leave);

10. *Hagy v. Sprint Cellular*
($4,000,000 settlement approved);

11. *Sandpiper Village Condominium Ass'n v. Louisiana-Pacific Corp.*,
($375,000,000.00 settlement) (defective hardboard siding;);

12. *Ottinger v. EMI Distribution, Inc.*
($65,000,000.00 nationwide settlement approved)
(price-fixing of compact discs);

13. *Sweet v. Ford Motor Co.*
($30,000,000 nationwide settlement approved as part of California settlement)
(multi-state class certified) (product defect);

14. *Friedman v. Union Bank of Switzerland, et al.*
($1,250,000,000,000.00 settlement);

15. *Fox v. American Cyanamid Co.*
($15,000,000.00 settlement) (vertical price-fixing conspiracy in pesticide market);

16. *Wilson v. Chesapeake Corp., et al.*
($600,000 Tennessee-only settlement) (horizontal price-fixing conspiracy in commercial tissue products market);

17. *Ferguson v. Columbia/HCA Healthcare Corp.*
($5,000,000 settlement) (overcharges in healthcare industry);

19. *Teeter v. State Farm Insurance Co.*
($1.2 Billion Jury Verdict - Affirmed by Illinois Court of Appeals. Presently pending before the Illinois Supreme Court);

20. *Freeman v. Champion International Corporation*
($2,400,000 settlement) (nuisance action which alleged unlawful pollution of Pigeon River in Tennessee);

21. *McCampbell v. F. Hoffman - LaRoche Ltd., et al.*
($10,000,000 Tennessee settlement approved) (price-fixing conspiracy in vitamins market);

22. *Milligan v. Food Lion Corp.*
($3,000,000 nationwide settlement) (unfair or deceptive practices in sales tax charges);

23. *Hunter v. Bank One*
($25,000,000 nationwide settlement) (class certified) (deceptive bank financing practices);

24. *Carter v. First Tennessee Bank*
($7,000,000 nationwide settlement) (class certified) (deceptive bank financing practices);

25. *Posey v. Dryvit Corp.*
($50,000,000 nationwide settlement) (product defect in synthetic stucco);

26. *Couch v. Brunswick Corporation*
(Nationwide settlement for consumers valued at $20,000,000) (monopolization of inboard and stern drive marine engine market);

27. *Coleman Properties, LLC v. AFG Industries*
(Tennessee settlement) (horizontal price-fixing conspiracy in flat glass industry);

28. *Sams v. Hoechst Aktiengesellschafat, et al.*
(Nationwide settlement approved) (conspiracy in Cardizem CD market);

29. *Beaudreau v. General Motors Corp.*
(Appeal pending) (unfair or deceptive automobile financing practices);

30. *Davis v. United States Tobacco Co., et al.*
(Multi-state settlement) (unfair restraint in trade in smokeless tobacco market);

31. *Freeman v. Blue Ridge Paper Co.*
(Nuisance action filed in 2003 against paper company for polluting Pigeon River in Tennessee);

32. *Lundsford v. Callaway Golf. Co.*
(Antitrust action for anti-competitive conduct in market for golf club clubs);

33. *Flanary v. Carl Gregory Dodge of Johnson City Tennessee LLC*
(Appeal pending) (Deceptive trade practices action against car dealer for illegal "processing fee" or "administrative charges");

34. *Beaudreau v. Larry Hill Pontiac*
(Deceptive trade practices action against car dealer for illegal "dealer participation" charges) (Appeal pending);

35. *Randolph v. Schering-Plough Corporation*
(Pending) (Antitrust action against pharmaceutical companies for agreeing to keep cheaper generic bio-equivalent drug of K-Dur 20 off the market);

36. *Gribble v. Glaxo Wellcome Inc.*
(Pending) (Deceptive trade practices action against pharmaceutical companies for marketing through false representations the safety attributes and side effects of the drug, Lotronex);

37. *Turnage v. Norfolk Southern Corporation*
(Pending) (Nuisance action against railroad for injunctive relief and damages

resulting from a train derailment in Blount and Knox County, Tennessee);

38. *Benson v. Nan Ya Plastics Corp.*
(Pending) (Price-fixing action against manufacturers of polyester staples);

39. *Raines v. Pharmacia Corporation*
(Pending) (Price-fixing action against manufacturers of weed killers Roundup® and Touchdown®);

40. *Daugherty v. Sony Electronics, Inc.*
(Pending) (Defective product/breach of warranty/deceptive trade practices action against manufacturer of DVD player);

41. *Bennett v. Visa U.S.A. Inc. and MasterCard International Inc.*
(Pending) (Antitrust action against credit card/debit card companies for overcharges paid by consumers as a result of attempted market monopolization);

42. *Silvey v. WorldCom Inc.*
(Pending) (Action against WorldCom and executives for violating Tennessee Securities Act by overstating revenue and stock value);

43. *Spartanburg Regional Healthcare System v. Hillenbrand Industries Inc.*
(Pending) (Antitrust action against Hill-Rom for attempting to monopolize specialty hospital bed market and illegally tying products);

44. *Sutton v. Stolt-Nielson Transportation Group Ltd.*
(Pending) (Antitrust action against shipping companies for bid-rigging/price-fixing transportation charges of liquid chemicals);

45. *Johnson v. General Motors Corp., et al*
(Pending) (Antitrust action against every major car manufacturer)

46. *Sutton v. Pfizer Inc., et al*
(Pending) (false representations made to FDA to obtain approval of Neurontin)

Significant Settlements or Judgments

Finally, Mr. Ball has also served as one of the counsel in several major consumer and antitrust class actions, including:

- ***Cox v. Shell Oil Company, et al***. This lawsuit filed by Mr. Ball and a number of other counsel filed this case in 1995 charging Shell Oil Company, E.I. du Pont de Nemours, and Hoescht Celanese with manufacturing and marketing defective polybutylene pipes and plumbing systems. The settlement provided a minimum of $950 million settlement in relief and is the largest class action settlement of its kind

in U. S. history.

- ***Friedman v. Union Bank of Switzerland, et al.*** Mr. Ball, along with co-counsel, represented a class of victims of the Holocaust whose assets were wrongfully retained by private Swiss Banks during or after World War II. The case raised novel issues of international banking law and international human rights law. A settlement was reached with the Swiss Banks in the sum of $1.2 Billion. Mr. Ball, and many of his co-counsel waived their attorney's fees.

- ***Infant Formula Consumer Antitrust Litigation***. Mr. Ball, along with co-counsel, instituted class actions in multiple state courts against three companies who conspired to drive up the price of infant formula. The cases resulted in an aggregate settlement of $64,000,000.00. Foremost among the cases was ***Blake v. Abbott Laboratories***, Civil Action Number L-8950 (Circuit Court, Blount Cty., Tennessee). ***Blake*** was the first opinion in the history of Tennessee jurisprudence granting indirect purchasers a private right of action under state antitrust and consumer protection laws.

Honors & Awards

In the late 1980's, Mr. Ball was selected to be included in the publication *"The Best Lawyers in America"* and has been included in every subsequent publication since 1989. In 1997, Mr. Ball was a recipient of a *Public Justice Achievement Award* by the *Trial Lawyers for Public Justice* for his work on behalf of consumers in the polybutylene pipe product liability litigation, which resulted in an unprecedented settlement providing a minimum of $950 million in relief and a potentially unlimited maximum recovery for property owners.

Telephone: 865.525.7028 ● Telecopier: 865.525.4679 ● gball@ballandscott.com

IN THE CIRCUIT COURT FOR COCKE COUNTY, TENNESSEE AT NEWPORT

BAUDA VAUDA LEE SUTTON,

Plaintiff,

v.

PFIZER, INC. and

WARNER-LAMBERT, CO., LLC

Defendants

Civil Docket No. 29,117-II

CLASS ACTION COMPLAINT

Plaintiff, BAUDA VAUDA LEE SUTTON, individually, and on behalf of all others similarly situated, for their complaint against Defendant, PFIZER, formerly known as WARNER-LAMBERT COMPANY, LLC, upon knowledge as to herself and her own acts, and upon information and belief as to all other matters, alleges as follows:

NATURE OF THE CASE

1. Plaintiff brings this Class action case for violation of the Tennessee Trade Practices Act ("TTPA"), T.C.A. §47-25-101, et seq., violation of the Tennessee Consumer Protection Act ("TCPA"), §47-18-104, et seq., money had and received, and unjust enrichment based upon Defendants' attempt to restrain trade through illegal marketing and advertising, leading to the sale of the drug, Neurontin, for unapproved or ineffective uses. Because of the fraudulent concealment and continuing violations alleged herein, the relevant statutes of limitations are either tolled, or are currently running.

2. This Class action case is brought by Plaintiff individually and on behalf of similarly

situated consumers in the State of Tennessee who have unwittingly paid millions of dollars to Defendants as a result of Defendants' illegal marketing of the prescription drug Neurontin. Defendants marketing scheme was designed to push and promote Neurontin for Unapproved or Off-Label uses, as defined herein, by persuading doctors to prescribe and consumers to request the prescription of Neurontin for such uses.

PARTIES

3. WARNER-LAMBERT COMPANY, LLC (hereinafter "WARNER-LAMBERT"), was a corporation operating and existing under the laws of the State of Delaware. Its principal place of business was Morris Plains, New Jersey. WARNER-LAMBERT can be served with process through its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

4. WARNER-LAMBERT was engaged, in part, in the development, manufacture, marketing, advertising, sale and distribution of prescription drugs intended for human use, specifically Neurontin, in the United States. WARNER-LAMBERT's pharmaceutical products were manufactured in Puerto Rico, and shipped to all fifty states and the District of Columbia. Specifically, Neurontin was marketed, advertised, sold and distributed in Tennessee, including Cocke County, Tennessee.

5. PFIZER, INC. ("PFIZER"), the world's largest pharmaceutical company, is a corporation operating and existing under the laws of the State of Delaware. Its principal place of business is New York, New York. PFIZER can be served with process through its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

6. PFIZER acquired WARNER-LAMBERT in 2000, and thereafter developed, manufactured, marketed, advertised, sold and distributed those prescription drugs intended for human use, including Neurontin, which were previously developed, manufactured, marketed, advertised, sold and distributed by WARNER-LAMBERT. PFIZER continued to market, advertise, sell and distribute Neurontin in Tennessee.

7. Certain doctors practicing in the State of Tennessee who prescribed Neurontin to Plaintiff and the Class members during the Class period are unnamed co-conspirators to various acts described herein.

8. Plaintiff, BAUDA VAUDA LEE SUTTON ("Sutton"), is a consumer and resident of Cocke County, Tennessee. She purchased Neurontin during the Class period. Plaintiff was prescribed, purchased and used Neurontin for the treatment of pain, which was an Unapproved (as defined herein) use of Neurontin.

JURISDICTION AND VENUE

9. Venue is proper in this judicial district because Plaintiff resides in Cocke County, Tennessee, was prescribed, purchased and used or consumed Neurontin in Cocke County, Tennessee, and Defendants transact business, and/or have agents in Tennessee, and because substantial trade and commerce described below have been carried out in Tennessee.

BACKGROUND

10. Neurontin was initially approved by the federal government for the treatment of epileptic seizures in patients whose conditions had not improved through the use of other types of treatment.

11. Although doctors are free to prescribe federally approved drugs for any use of their

choosing, pharmaceutical companies are prohibited from promoting drugs for non-approved purposes. Many of the doctors who were targeted by Defendants to prescribe Neurontin were not even practicing in the field of medicine relevant to Neurontin's Approved use.

12. WARNER-LAMBERT and PFIZER paid for and encouraged doctors to prescribe Neurontin to patients for the treatment of, among other ailments, bipolar disorder, Lou Gehrig's disease, ADD, restless leg syndrome and drug and alcohol withdrawal seizures, all Unapproved uses.

13. Defendants have marketed Neurontin for prescription of dosage amounts greater than those approved for FDA labeling.

14. Further, Defendants have marketed Neurontin for Unapproved uses without conducting studies or publishing reports of the interaction between Neurontin and the use of other drugs related to the treatment of those Unapproved uses.

15. Neurontin has become one of the biggest-selling drugs in the world. Off-Label uses of Neurontin have grown to 94% as of 2002. Sales in 2003, have been estimated at $2.7 billion, at least ninety percent (90%) of which came from the sale of the drug for Unapproved uses.

16. On May 11, 2004, Warner Lambert entered into a plea agreement for distribution of an unapproved new drug (violation of 21 USC 331(d), 333(a)(2), and 355(a)) and distribution of a misbranded drug (for inadequate directions for use) (violation of 21 USC 331(a), 333(a)(2), and 352(f)(1)) in the *United States District Court of Massachusetts in the United States of America v. Warner-Lambert Company, LLC*, case no. 1:04-cr-10150-01-RGS. This plea was accepted by the court and Warner-Lambert was adjudicated and sentenced on June 9, 2004, by the Honorable Richard G. Stearns. (A copy of the Judgment and transcript of the Plea Hearing are attached

attached hereto as **EXHIBITS 1 and 2**, respectively).

INTRASTATE TRADE AND COMMERCE

17. During all or part of the Class period, Defendants manufactured, sold and distributed substantial amounts of Neurontin, in a continuous and uninterrupted flow of commerce throughout the United States and across state lines, into Tennessee, where the product was then sold, or offered for sale.

18. In connection with the marketing, advertising, distribution and sale of Neurontin, during all of the Class period, Defendants transmitted funds, contracts, bills and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines, into the State of Tennessee.

19. Because of the fraudulent concealment described below, any applicable statute of limitations affecting or limiting the rights of action by Plaintiff or members of the Class has been tolled.

CLASS ACTION

20. Plaintiff brings this Class Action, pursuant to Rule 23 of the Tennessee Rules of Civil Procedure, as representative of the following Class:

(a) All consumers in the State of Tennessee who purchased and/or paid all or part of the purchase price of Neurontin for themselves, their families, or their members or insureds in the State of Tennessee (the "Class"), during the period from 1995 to the present (the "Class Period").

(b) Excluded from the Class are the Defendants, their respective subsidiaries and affiliates, and the court assigned to this case, including its employees and their family members.

21. There are so many Class members that joinder is impracticable. There are, at a minimum, thousands of Neurontin purchasers in Tennessee.

22. Plaintiff's claims are typical of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

23. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are similar, and not antagonistic, to those of the Class.

24. Plaintiff is represented by counsel who are experienced and competent in the prosecution of complex class action litigation.

25. Questions of law and fact common to all members of the Class predominate over questions, if any, that may affect only individual members, because Defendant has acted on grounds generally applicable to the entire Class. Questions of law and fact common to the Class include:

(a) Whether Defendants disseminated false and/or deceptive information to doctors in an attempt to convince doctors to prescribe Neurontin to their patients for treatment purposes which had not been approved by the federal government.

(b) Whether Defendants disseminated false and/or deceptive information to the general public in an attempt to get members of the general public to convince their doctors to prescribe Neurontin for treatment purposes which had not been approved by the federal government.

(c) Whether Defendants'actions concerning the sale and marketing of Neurontin have violated , and continue to violate, the TTPA.

(d) Whether Defendants' actions concerning Neurontin have violated , and

continue to violate, the TCPA.

(e) Whether Defendants were unjustly enriched as a consequence of their unlawful, unfair and deceptive acts.

(f) Whether, and to what extent, the conduct of Defendants caused injury to Plaintiff and the Class, and if so, the appropriate measure of damages.

26. Class action treatment is a superior method for the fair and efficient adjudication of the issues, in that, among other things, such treatment will permit a large number of similarly situated consumers to prosecute their common claims in a single forum simultaneously, efficiently, and economically, and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would entail. The benefits from class action treatment, including providing damaged class members with a method of obtaining redress for claims that might not be practicable to pursue on an individual basis, substantially outweigh any difficulties in management of the suit as a class action.

THE FACTS

27. The Federal Food, Drug and Cosmetic Act ("FFA"), governs the lawful interstate distribution of drugs for human use. The FFA regulations require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA"). 21 U.S.C. §355(b).

28. In such case, the NDA sponsor is required to submit proposed labeling to the U.S. Food and Drug Administration ("FDA"), for the proposed intended uses for the drug including, among other things, the conditions for therapeutic use. The NDA must also provide data from randomized and well-controlled clinical trials that demonstrate that the drug will be safe and

effective when used in accordance with the proposed labeling.

29. Without NDA approval, any new drug is prohibited from introduction into interstate commerce. Once the NDA and proposed labeling are FDA approved, the sponsor is permitted to promote and market the drug only for the medical conditions specified for use in the approved labeling. Uses which have not been FDA approved are known as "Unapproved" or "Off-Label" uses.

30. Before a drug can be labeled or promoted for a use different from the FDA approved uses, the sponsor is required to submit a new, or amend an existing, NDA. This too, requires submission of data from randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would b safe and effective for the newly proposed use or uses.

31. A drug is misbranded if the labeling does not contain adequate directions for use. If the label contains directions for Unapproved uses, the directions would be misleading and the drug misbranded.

32. 21 U.S.C. §§ 331(a)(d), 333(a) and 355, prohibit distribution in interstate commerce of an unapproved new drug or misbranded drug.

33. In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a new drug, Neurontin (known chemically as gabapentin). The application sought approval for Neurontin only for use as an adjunctive therapy in the treatment of partial seizures, with and without secondary generalization, in adults with epilepsy. Adjunctive therapy limits the prescription of the drug such that it cannot be prescribed as the lone treatment of epilepsy, but as an add-on drug in cases where a primary anti-epilepsy drug is not successful. On or about December 30, 1993, the FDA approved Neurontin only for that specific use (the "Approved "

use).

34. From at least June, 1995, through at least August 20, 1996, Unapproved uses for Neurontin included, but were not limited to, post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, "Enumerated Unapproved Uses." The market for Neurontin's Off-Label uses for pain management, psychiatric disorders, anxiety and depression, were much larger than the market for epilepsy adjunctive therapy alone.

35. WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of the Enumerated Unapproved Uses during the Class Period.[1]

36. WARNER-LAMBERT conducted an evaluation of the market potential for certain of the Unapproved uses for Neurontin including, but not limited to, post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

37. Some of WARNER-LAMBERT's annual strategic marketing plans and planning documents for Neurontin included quarterly and annual budget, goals, objectives, strategies, and tactics for increasing sales for Unapproved uses.

38. From early 1995, on repeated occasions, WARNER-LAMBERT specifically determined not to seek FDA approval for certain Unapproved uses.

39. Instead, Defendants recognized the potential for significant profit in the Off-Label promotion of Neurontin for Unapproved uses and at higher dosages even though there was little,

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[1]Of the Enumerated Unapproved Uses, only post-hepatic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described herein.

if any, scientific evidence suggesting Neurontin was safe and effective for such uses.

40. A July 1995 assessment of Neurontin's market potential for neuropathic pain stated that there was no intention to develop the use at that point, which would have required submission of an NDA for FDA approval.

41. In or about the fall of 1995, WARNER-LAMBERT created a planning document for the sale and marketing of Neurontin including conference calls on pain and a pain consultant meeting, and referring to Neurontin as a pain treatment.

42. In a 1995 Marketing Assessment of proposed psychiatric uses for Neurontin, WARNER-LAMBERT forecast potential revenue from sales of Neurontin for Unapproved uses of bipolar and anxiety treatment taking into consideration both FDA approval and non-approval. WARNER-LAMBERT reviewed the potential psychiatric uses and concluded that the company would not seek FDA approval for these Unapproved uses of Neurontin.

43. Two of the principal factors behind the determination to limit FDA approval for Neurontin involved the short patent protection available for Neurontin, and the potential competition with the sale of another drug developed by WARNER-LAMBERT of which FDA approval was expected for use of the new drug for treatment of some of Neurontin's Unapproved uses.

44. From at least June, 1995 through August, 1996, WARNER-LAMBERT promoted the sale and use of Neurontin for other than Approved uses through the use of promotions through sales representatives, Medical Liaisons, consultants' meetings and advisory boards, and teleconferences, grants and studies, to name a few.

45. Defendants' marketing schemes were carried out through the use of the following

actions:

- illegal direct solicitation of doctors for Unapproved or Off-Label uses;
- making false statements to doctors concerning the safe and efficient use of Neurontin for Off-Label and Unapproved uses;
- illegal kickbacks to doctors who wrote a high number of prescriptions for Neurontin for Off-Label purposes to patients such as Plaintiff and the Class members who purchased Neurontin;
- creation of a group of employees who were misleadingly titled "medical liaisons" which did not include any legitimate scientific or medical activity, but who actually acted as conventional direct sales persons;
- specially training Defendants' employees in ways to illegally solicit doctors in the Unapproved or Off-Label uses of Neurontin in an effort to avoid or get around the laws limiting solicitation of doctors for such uses;
- offering or paying Defendants' employees to maintain their silence as to Defendants' illegal activities described, in part, herein;

SALES REPRESENTATIVES PITCHING NEURONTIN FOR UNAPPROVED USES

46. In October 1995, a memorandum from a member of WARNER-LAMBERT's Epilepsy Disease Team noted that data purchased from an outside vendor showed that doctors had reported the main sales pitch from 10 of 50 WARNER-LAMBERT's sales representatives was for the Off-Label use of Neurontin.

47. In 1996, a sales representative created a document entitled "Neurontin Can Do/Can't Do," which suggested that sales reps ask doctors whether they ever used "other" anti-epileptic

drugs for painful neuropathies, and mentioning that approximately 35% of all Neurontin use is for non-seizure. The document also suggested using lunch programs to pitch Neurontin and pain.

48. At least as early as July 1996, WARNER-LAMBERT sales representatives were meeting with doctors to discuss the use of Neurontin for the treatment of pain.

USE OF MEDICAL LIAISONS TO PROMOTE UNAPPROVED USES OF NEURONTIN

49. WARNER-LAMBERT employed "Medical Liaisons" who worked with sales representatives in preparation of and sales presentations to physicians and physicians' groups. Medical Liaisons were introduced as specialists in the drug they were presenting, which was untrue. Medical Liaisons and sales persons were encouraged to represent the Medical Liaisons as medical researchers or physicians, both of which were untrue.

50. In 1996, a WARNER-LAMBERT Medical Director sent a voice mail to the Medical Liaison in his territory urging them to make the sale of Neurontin for pain their main sales focus. This message was interpreted by the Medical Liaisons as meaning that they should promote Neurontin for Unapproved uses, and this was done on one occasion specifically promoting Neurontin for the Unapproved use of treatment for neuropathic pain.

51. On at least one occasion a Medical Liaison promoted the use of Neurontin for Unapproved uses to a group of physician members of a local medical society, and the presentation was highly acclaimed by WARNER-LAMBERT officials.

52. Medical Liaisons were used to make false sales pitches to doctors regarding scientific information concerning the following Off-label uses of Neurontin: Bipolar Disorder, Peripheral Neuropathy, Diabetic Neuropathy, and other Pain Syndromes, Epilepsy Monotherapy, Reflex Sympathetic Dystrophy, Attention Deficit Disorder, Restless Leg Syndrome, Trigeminal

Neuralgia, Post-Herpetic Neuralgia, Essential Tremor Periodic Limb Movement Disorder, Migraine Headaches, and Drug and Alcohol Withdrawal Seizures. In most cases, Medical Liaisons informed the doctors that certain studies, reports or scientific evidence existed with respect to using Neurontin in the successful treatment of the above Off-label uses, when in fact no such study, report or evidence existed, such were inconclusive, or the only support for these claims was based on anecdotal evidence of nominal scientific value, rather than scientific or clinical trial data. Further, references to reports or evidence which did exist were primarily those which had been created or sponsored by Defendants as mere "studies."

USE OF CONSULTANT AND ADVISORY BOARD MEETINGS TO PROMOTE UNAPPROVED USES OF NEURONTIN

53. On numerous occasions, Defendants paid kickbacks to doctors who attended "consultants' meetings," the purposes of which were to promote and encourage the Off-label uses of Neurontin. Defendants disguised these kickbacks as "consultantships" since the federal rules prohibit kickbacks in exchange for prescribing a particular drug.

54. Under this scheme, Defendants solicited and paid doctors to attend dinners or conferences to listen to lengthy presentations of Off-label uses of Neurontin. These doctors were acting as "consultants" at these meetings, and some doctors even signed sham consulting agreements.

55. The presentations were made by Defendants' employees or doctors hired by Defendants for the purpose of promoting Neurontin. Attendees were solicited to ask questions about Neurontin, and in some instances Defendants posed questions to the speakers about the Off-label uses of Neurontin to expose the attendees to such information.

56. At some meetings, the consultants were asked if they would write more prescriptions for Neurontin as a result of the meeting. This would have been an irrelevant question if the true purpose of the meeting was to receive the consultants' advice. Defendants even used outside third party marketing firms to track whether the attendees had written more Neurontin prescriptions after the meetings. This was only relevant data if the true purpose of the paid meetings was to solicit the attendees to prescribe more Neurontin.

57. In 1996,a consultants' meeting was put on by WARNER-LAMBERT with approximately 42 physicians in attendance, invited in part based on the large number of prescriptions for Neurontin the physicians had written. Although the presentations were provided by Proworz, an independent company, Defendants created, monitored and approved all aspects of the program, including selection of the speakers, selection of the topics for presentation, and approval of the presentation contents. Two half-day presentations were given relating to Neurontin, in which nine physicians gave presentations related to the use of Neurontin for treatment of Unapproved uses. Two other presentations were made at the 1996 consultants' meeting in which the use of Neurontin for the Unapproved use of pain treatment was promoted and urged.

58. The faculty doctors at the consultants' meeting were paid between $1,500 and $2,000 each for their presentations. Additionally, WARNER-LAMBERT paid for accommodations, meals and an honorarium to each doctor who attended.

59. Between 1995 and 1997, Defendants hosted at least twenty-two (22) consultants' meetings, similar in nature to the above described 1996 consultants' meeting. Although some meetings were not as elaborate or expensive as the 1996 meeting described above, many

meetings involved expensive dinners at local restaurants in which $200 "honorariums" were paid to the doctors who attended.

60. Following one of the 1996 consultants' meetings, the promotional materials from the meeting were generated to some of the WARNER-LAMBERT employees, with accolades of the messages delivered about the use of Neurontin. As a follow-up to the meeting, certain WARNER-LAMBERT employees were asked to track the effects of the meeting on physicians who had attended based on the number of prescriptions they were writing for Neurontin.

61. At a 1996 advisory board meeting, WARNER-LAMBERT instructed some of the speaking physicians to address Unapproved uses of Neurontin, and some did so. WARNER-LAMBERT paid all expenses for the doctors at this meeting and also paid all expenses for their spouses, including attendance at the Olympics and closing ceremonies.

62. A 1996 memorandum to WARNER-LAMBERT sales representatives listed two goals: the use of Medical Liaisons to target the Neurontin pain and psychiatric market and the use of pain teleconferences moderated twice weekly by key neuro consultants, to 250 physicians quarterly.

63. Teleconferences by WARNER-LAMBERT have been utilized to promote Neurontin for Off-Label uses. These teleconferences have been conducted by employees, pain specialists, Medical Liaisons and at least on one occasion, by a WARNER-LAMBERT Medical Director.

USE OF GRANTS AND STUDIES TO BOOST NEURONTIN SALES

64. Defendants used payments, in the form of grants and studies to reward loyal Neurontin prescribers.

65. Defendants awarded at least twelve (12) "educational grants" to physicians who

were willing to prescribe Neurontin or programs which were willing to host Neurontin advocacy speakers. These grants were charged to the Neurontin marketing budget.

66. Defendants also paid at least nine (9) leading Neurontin prescribers to conduct advocacy "studies" of Neurontin which were actually of questionable scientific credibility. The doctors did not engage in significant work for these studies, which often required little more than gathering and writing up office notes or records. These studies were not reported to the FDA, or were concealed from the FDA, because Defendants knew they would not be deemed studies by the FDA since the "research" had no scientific value.

67. One study, the STEPS program, financially rewarded physicians for prescribing large amounts of Neurontin. STEPS was couched as a clinical research trial, but targeted neurologists to prescribe Neurontin at higher doses than indicated by the FDA approved labeling. The STEPS program called for over 1,200 "investigators" to enroll a few patients each. The physicians were instructed to demonstrate that their patients could tolerate high dosages of Neurontin by putting their patients on higher dosages of Neurontin than FDA labeling allowed. The physicians were paid not only for participating in the study, but for every patient enrolled. The physicians were offered payments of additional case for each patient the doctor kept on Neurontin after the study ended.

68. As well, given the nature of the study, STEPS had the effect of encouraging physicians to place non-study patients on Neurontin on higher doses than found effective by the FDA. Of course, the STEPS program was designed and intended to result in increased sales of Neurontin due to higher per patient dosages sold.

COUNT I: VIOLATION OF THE TENNESSEE TRADE PRACTICES ACT T.C.A. §47-25-101, ET SEQ.

69. Plaintiff incorporates by reference all of the preceding paragraphs of this Complaint as though fully set forth herein.

70. Defendants made the above misrepresentations to doctors knowing and intending that the doctors would rely on these misrepresentations when prescribing Neurontin to their patients. As a result, the doctors did so, and consequently provided inaccurate and untruthful medical advice to their patients.

71. Defendants are liable to the Plaintiff and the Class for violation of the TTPA for arranging, contracting, agreeing or combining with persons or corporations with a view to lessen, or to tend to lessen, full and free competition in the importation or sale of Neurontin into Tennessee, and such arrangements contracts, agreements or combinations with persons or corporations were designed or tended to advance, reduce or control the price or the cost of Neurontin to the consumers of the State of Tennessee, in violation of the Tennessee Trade Practices Act, T.C.A. §47-25-101, et seq.

72. As a direct and proximate result of the aforesaid violations of TTPA, Plaintiff and the Class members have suffered financial losses and, as such are entitled to recover the full consideration or sum paid by such persons for Neurontin.

73. Plaintiff and the Class members are also entitled to an injunction restraining Defendants from the sale of Neurontin in Tennessee.

COUNT II: VIOLATION OF THE TENNESSEE CONSUMER PROTECTION ACT OF 1977 T.C.A. § 47-18-104, ET SEQ.

74. Plaintiff incorporates by reference paragraphs 1 through 46 of this Complaint as

though fully set forth herein.

75. Defendants disseminated false and misleading information to consumers and others in the United States, including Tennessee, stating or insinuating that the United States Food and Drug Administration ("FDA") approved Neurontin for the treatment of Unapproved uses.

76. Defendants disseminated false and misleading information to consumers and others in the United States, including Tennessee, claiming that Neurontin had been effective in the treatment of certain ailments, when in fact, the use of Neurontin was no more effective than the use of placebo.

77. Defendants knew that the false and misleading information to consumers and others, would come at the direct expense of consumers in the United States, including Tennessee, who pay for and consume prescription drugs.

78. Defendants' misrepresentations deceived or tended to deceive Plaintiff and Class members as to the approved, beneficial and intended uses of Neurontin.

79. Defendants' misrepresentations influenced purchasing decisions of consumers and others, including Plaintiff and Class members.

80. Defendants' misrepresentations injured or were likely to injure Plaintiff and Class members.

81. Defendants are liable to Plaintiff and the Class for violation of the following, under the Tennessee Consumer Protection Act of 1977, T.C.A. §47-18-101, et seq.:

a) For causing the likelihood of confusion or of misunderstanding as to the approval or certification of Neurontin for the purposes of which it was marketed and sold to Plaintiff and the Class, T.C.A. §47-18-104(b)(2);

b) For representing that Neurontin had approval for uses or benefits that Neurontin did not have, T.C.A. §47-18-104(b)(5)

c) For using statements or illustrations in advertising Neurontin which created a false impression of the grade, quality, make, value or usability of Neurontin, or which may have otherwise misrepresented Neurontin in such a manner that later, on disclosure of the true facts, there is a likelihood that Plaintiff and Class members may be switched from Neurontin to other drugs, T.C.A. §47-18-104(b)(21);

d) For otherwise engaging in the above enumerated acts or practices in the sale and/or marketing of Neurontin which were deceptive to consumers in the State of Tennessee, T.C.A. §47-18-104(b)(27).

82. Defendants' unfair or deceptive acts were in willful and knowing violation of the TCPA, entitling Plaintiff and the Class to treble damages as well as such other relief as the court determines necessary and proper.

83. Plaintiff and the Class members are also entitled to an injunction restraining Defendants from the sale of Neurontin in Tennessee.

COUNT III: UNJUST ENRICHMENT/RESTITUTION

84. Plaintiff realleges and incorporates by reference all of the foregoing paragraphs.

85. Defendants have been unjustly enriched by the illegal sale and marketing of Neurontin. Plaintiff and Class members demand that Defendants be ordered to return all monies illegally collected from Plaintiff and Class members, plus interest in violation of the antitrust and consumer protections laws of Tennessee. Plaintiff does not seek disgorgement of any common and/or undivided fund, but seeks as restitution only those monies illegally collected from them as

a result of the unfair or deceptive conduct described herein.

86. Defendants have benefitted from their illegal restraints of trade and unfair or deceptive acts and practices through the illegal sale and marketing practices resulting in damages to Plaintiff and Class members who paid for Neurontin.

87. It would be inequitable to permit Defendants to retain any of the illegal gotten monies paid for Neurontin.

COUNT IV: MONEY HAD AND RECEIVED

88. Plaintiff realleges and incorporates by reference all of the foregoing paragraphs.

89. Defendants, through their unlawful conduct, have reaped substantial profits from the payment by Plaintiff and Class members for Neurontin. Plaintiff and Class members have conferred a benefit upon Defendants through a mistake of fact. In equity and good conscience, Defendants should not be allowed to retain this benefit. Plaintiff and Class members demand that Defendants be ordered to return all such monies illegally collected, plus pre-judgment interest.

90. Based upon the foregoing illegal, unfair, or deceptive conduct, and the resulting payments made by Plaintiff and the Proposed Class members for Neurontin, Defendants owe Plaintiff and the Proposed Class members for money had and received.

FRAUDULENT CONCEALMENT, CONTINUING VIOLATIONS AND EQUITABLE TOLLING

91. Plaintiff realleges and incorporates by reference all of the foregoing paragraphs.

92. Plaintiff and Class members did not discover, and could not discover through the exercise of reasonable diligence, the existence of the claims sued upon until recently because

Defendants actively, intentionally, and fraudulently concealed the existence of the arrangements, contracts, agreements or combination to illegally market and sell Neurontin from Plaintiff and the Class by one or more of the following affirmative acts:

(a) Marketing Neurontin for treatment of Unapproved uses;

(b) Soliciting doctors to prescribe Neurontin for the treatment of Unapproved uses;

(c) Concealing publication of reports which found that Neurontin was no more effective in treating unapproved uses than other drugs, or placebos, yet representing to physicians and the general public that Neurontin was more effective in treating those Unapproved uses than other drugs.

93. Any applicable statutes of limitation have been tolled by Defendants' affirmative acts or concealment and continuing misrepresentations. Through such affirmative acts of concealment, misrepresentation and continuing sales of Neurontin for Unapproved uses, Defendants have been able to conceal from Plaintiff and Class members the truth about the effective and Approved uses of Neurontin, tolling the running of the applicable statutes of limitation.

94. Because of the self-concealing nature of Defendants' actions, and their affirmative acts of concealment and misrepresentation, Plaintiff asserts the tolling of any applicable statutes of limitations affecting her claims. Defendants' unlawful conduct is also continuing, tolling the applicable statute of limitations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class pray that the Court enter judgment as follows:

A. Declaring and certifying this action as a proper class action and Plaintiff as the proper class representative;

B. On Counts I and II:

1. On Count I, that the Court find, adjudge and decree that Defendants have engaged in an illegal agreement, arrangement, contract or combination in violation of the Tennessee Trade Practices Act, T.C.A. §47-25-101, et seq., and that the Court award Plaintiff and Class members their full consideration paid, injunctive relief and for all other damages available.

2. On Count II, that the Court find, adjudge and decree that the Defendants have engaged in unfair or deceptive practices in violation of the Tennessee Consumer Protection Act of 1977, T.C.A. §47-18-101, et seq., and award Plaintiff and Class members: (a) actual damages in a amount to be proved at trial, plus interest and costs; (b) treble damages, where appropriate, for all losses and injuries suffered as a result of Defendants' illegal actions, with the amount of damages to be determined at trial; c) injunctive relief; and, (d) appropriate restitution.

C. On Count III, that the Court find, adjudge and decree that Defendants have received payments from Plaintiff and Class members that they were not justly entitled to receive, and that the Court award Plaintiff and the Class restitution for Defendants' unjust enrichment, plus pre-judgment interest.

D. On Count IV, that the Court find, adjudge and decree that Defendants have received monies which they were not entitled to lawfully receive or retain and that Plaintiff and Class receive compensatory damages for their injuries, plus pre-judgment interest and costs.

E. That the Court order such other, further and general relief as the Court may deem just

and proper, including prejudgment interest on all counts.

Respectfully submitted, this the 6th day of August, 2004.

ATTORNEYS FOR PLAINTIFF

Gordon Ball
Ball & Scott
550 W. Main Avenue, Suite 750
Knoxville, TN 37902
(865) 525-7028

Shelly L. Wilson
Robertson & Overbey
The Farragut Building
530 South Gay Street, Suite 802
Knoxville, Tennessee 37902-1537
(865) 521-3010

IN THE CIRCUIT COURT FOR COCKE COUNTY, TENNESSEE
AT NEWPORT

BAUDA VAUDA LEE SUTTON,

Plaintiff,

v.

PFIZER, INC. and

WARNER-LAMBERT, CO., LLC

Defendants

Civil Docket No. 29,117-II

COST BOND

We acknowledge ourselves sureties for costs in this action.

CIRCUIT COURT
FILED
AUG 11 2004
PEGGY W. LANE
CIRCUIT COURT CLERK
Cocke County, TN

ATTORNEYS FOR PLAINTIFF

Gordon Ball
Ball & Scott
550 W. Main Avenue, Suite 750
Knoxville, TN 37902
(865) 525-7028

AO 245B Sheet 1 - Judgment in a Criminal Case - D. Massachusetts (10/01)

United States District Court

District of Massachusetts

ORIGINAL

UNITED STATES OF AMERICA
V.
WARNER-LAMBERT COMPANY, LLC

JUDGMENT IN A CRIMINAL CASE
(For Offenses Committed On or After November 1, 1987)

Case Number: 1: 04 CR 10150 01 RGS

ROBERT FISKE, JR.
Defendant's Attorney

☐

THE DEFENDANT:

☒ pleaded guilty to count(s): 1 AND 2 OF AN INFORMATION
☐ pleaded nolo contendere to counts(s)_____ which was accepted by the court.
☐ was found guilty on count(s) _____ after a plea of not guilty.

Accordingly, the court has adjudicated that the defendant is guilty of the following offense(s):

Title & Section	Nature of Offense	Date Offense Concluded	Count Number(s)
21 USC 331(d), 333(a)(2), 355(a)	DISTRIBUTION OF AN UNAPPROVED NEW DRUG	08/20/96	1
21 USC 331(a), 333(a)(2), 352(f)(1)	DISTRIBUTION OF A MISBRANDED DRUG (Inadequate Directions for use)	08/20/96	2

☐ See continuation page

The defendant is sentenced as provided in pages 2 through 3 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on counts(s) _____ and is discharged as to such count(s).

☐ Count(s) _____ is dismissed on the motion of the United States.

IT IS FURTHER ORDERED that the defendant shall notify the United States Attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant shall notify the court and United States Attorney of any material change in the defendant's economic circumstances.

Defendant's Soc. Sec. No.:

Defendant's Date of Birth:

Defendant's USM No.:

Defendant's Residence Address:

Defendant's Mailing Address:
Same as above

06/07/04
Date of Imposition of Judgment

Richard G. Stearns
Signature of Judicial Officer

The Honorable Richard G. Stearns
Name and Title of Judicial Officer

Judge, U.S. District Court

Date 6-9-04.

EXHIBIT 1

CASE NUMBER: 1:04 CR 10150 01 RGS
DEFENDANT: WARNER-LAMBERT COMPANY, LLC

CRIMINAL MONETARY PENALTIES

The defendant shall pay the following total criminal monetary penalties in accordance with the schedule of payments set forth on Sheet 5, Part B.

	Assessment	Fine	Restitution
TOTALS	$800.00	$240,000,000.00	

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

☐ The defendant shall make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid in full prior to the United States receiving payment.

Name of Payee	*Total Amount of Loss	Amount of Restitution Ordered	Priority Order or Percentage of Payment

☐ See Continuation Page

TOTALS	$0.00	$0.00

☐ If applicable, restitution amount ordered pursuant to plea agreement _____

☐ The defendant shall pay interest on any fine or restitution of more than $2,500, unless the fine or restitution is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 5, Part B may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest, and it is ordered that:

☐ the interest requirement is waived for the ☐ fine and/or ☐ restitution.

☐ the interest requirement for the ☐ fine and/or ☐ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18, United States Code, for offenses committed on or after September 13, 1994 but before April 23, 1996.

CASE NUMBER: 1:04 CR 10150 01 RGS
DEFENDANT: WARNER-LAMBERT COMPANY, LLC

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties shall be due as follows:

A ☐ Lump sum payment of _____ due immediately, balance due

☐ not later than _____, or
☐ in accordance with ☐ C, ☐ D, or ☐ E below; or

B ☐ Payment to begin immediately (may be combined with C, D, or E below); or

C ☐ Payment in _____ (e.g., equal, weekly, monthly, quarterly) installments of _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

D ☐ Payment in _____ (e.g., equal, weekly, monthly, quarterly) installments of _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after release from imprisonment to a term of supervision; or

E ☒ Special instructions regarding the payment of criminal monetary penalties:

THE SPECIAL ASSESSMENT SHALL BE PAID FORTHWITH;

THE FINE SHALL BE PAID WITHIN 15 DAYS OF THE DATE OF IMPOSITION OF SENTENCE.

Unless the court has expressly ordered otherwise in the special instruction above, if this judgment imposes a period of imprisonment, payment of criminal monetary penalties shall be due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court, unless otherwise directed by the court, the probation officer, or the United States attorney.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Case Number, Defendant Name, and Joint and Several Amount:

☐ The defendant shall pay the cost of prosecution.

☐ See Continuation Page

☐ The defendant shall pay the following court cost(s):

☐ The defendant shall forfeit the defendant's interest in the following property to the United States:

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) community restitution, (6) fine interest (7) penalties, and (8) costs, including cost of prosecution and court costs.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

* * * * * * * * * * * * * * * * *
UNITED STATES OF AMERICA *
*
vs. * CRIMINAL ACTION
* No. 04-10150-RGS
WARNER-LAMBERT COMPANY LLC *
*
* * * * * * * * * * * * * * * * *

BEFORE THE HONORABLE RICHARD G. STEARNS
UNITED STATES DISTRICT JUDGE
WAIVER, CHANGE OF PLEA AND SENTENCING HEARING

A P P E A R A N C E S

OFFICE OF THE UNITED STATES ATTORNEY
1 Courthouse Way, Suite 9200
Boston, Massachusetts 02210
for the United States
By: Thomas E. Kanwit, AUSA
Sara M. Bloom, AUSA
Jill Furman, Trial Attorney

DAVIS POLK & WARDWELL
450 Lexington Avenue
New York, New York 10017
for the defendant
By: Robert B. Fiske, Jr, Esq.
James P. Rouhandeh, Esq.
Martine M. Beamon, Esq.

Courtroom No. 21
John J. Moakley Courthouse
1 Courthouse Way
Boston, Massachusetts 02210
June 7, 2004
2:30 p.m.

EXHIBIT 2

APPEARANCES, CONTINUED

HARE & CHAFFIN
160 Federal Street, 23rd Floor
Boston, Massachusetts 02110-1701
for the defendant
By: David B. Chaffin, Esq.

CAROL LYNN SCOTT, CSR, RMR
Official Court Reporter
One Courthouse Way, Suite 7204
Boston, Massachusetts 02210
(617) 330-1377

PROCEEDINGS

THE CLERK: Court is open. You may be seated.

This is United States of America versus Warner-Lambert Company, Criminal No. 04-10150.

Would all counsel please identify themselves for the record.

MR. KANWIT: Good afternoon, Your Honor. Thomas Kanwit for the United States.

MS. FURMAN: Good afternoon, Your Honor. Jill Furman for the United States.

MS. BLOOM: Sara Bloom on behalf of the United States.

MR. CHAFFIN: Good afternoon, Your Honor. David Chaffin for the defendant Warner-Lambert Company LLC.

And Your Honor has admitted previously pro hac vice, on my furthest right Robert Fiske from Davis Polk & Wardwell.

MR. FISKE: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MR. CHAFFIN: Attorney Jim Rouhandeh, Davis Polk & Wardwell.

MR. ROUHANDEH: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MR. CHAFFIN: This is Martine Beamon from Davis Polk & Wardwell --

MS. BEAMON: Good afternoon.

MR. CHAFFIN: -- also admitted pro hac vice.

And this is Martin Teicher who is the vice president of Warner-Lambert Company LLC.

Thank you, Your Honor.

MR. TEICHER: Good afternoon, Your Honor.

THE COURT: Mr. Rouhandeh, I understand you are going to be the principal spokesperson for the defense?

MR. ROUHANDEH: Yes, that's correct, Your Honor.

THE COURT: All right.

Just to inventory what's before me, I received a copy of the plea agreement, a copy of the Information that is proposed to be filed in this case, a copy of the settlement agreement entered in the related qui tam action, the Sentencing Memorandum supplied by the government and a similar memorandum supplied on behalf of the defendant Warner-Lambert, one letter from outside counsel objecting to some of the terms of the plea agreement which I think is alluded to in the government's sentencing memorandum.

And further I received today a proposed waiver of indictment in the case and a secretary's certificate certifying that the Board of Directors has designated Mr. Teicher to represent the company as attorney in fact.

So why don't we begin by swearing in Mr. Teicher.

THE CLERK: Mr. Teicher, would you stand and raise your right hand, please.

Martin Teicher, on behalf of Warner-Lambert Company do you solemnly swear that you will tell the truth, the whole truth and nothing but the truth in the matter now in hearing, so help you God?

MR. TEICHER: I do.

THE CLERK: Please take a seat right up there (indicating), sir.

Mr. Rouhandeh, if you would just stand beside him, please.

THE COURT: Mr. Teicher, my name is Richard Stearns. I am a judge of the United States District Court. I am going to be asking some questions as this proceeding transpires.

I think most of these questions are going to be very familiar to you, as I am sure your attorneys have very carefully prepared for this presentation today.

But should anything I say seem confusing or any question seem imprecise, either ask me to rephrase it or feel free to consult with counsel before you answer. All right?

MR. TEICHER: Thank you, Your Honor.

THE COURT: Can you tell us your full name and title for the record.

MR. TEICHER: My name is Martin Teicher. I am a Vice President of Warner-Lambert Company LLC.

THE COURT: All right. Mr. Teicher, you are familiar with what purports to be the minutes of the meeting held by the managers of Warner-Lambert on May 11, 2004?

MR. TEICHER: I am on the Board of Directors of Warner-Lambert.

THE COURT: And this resolution authorizes you to, in fact, appear for Warner-Lambert as attorney in fact; am I correct?

MR. TEICHER: Yes.

THE COURT: And the action of the Board of Directors in enacting this resolution was in the authority of the Board under the Articles of Incorporation?

MR. TEICHER: I believe so, Your Honor.

THE COURT: All right. Have you discussed -- and, again, I am asking more by way of formality, but it is an important question.

Have you discussed with counsel what it means for the corporation to waive indictment in this case?

MR. TEICHER: Yes.

THE COURT: Do you understand that the crimes, although they are treated as felonies because of a prior conviction of the company, are nonetheless charged as misdemeanors? Ordinarily the prosecutor has no authority on

his or her own to bring in the form of an indictment a felony or a charge with the consequence of a felony crime without obtaining the prior permission of a citizen panel called a grand jury to do so.

By waiving indictment in this case, Warner-Lambert is permitting the government to proceed as if it, indeed, had the consent of the grand jury to bring these charges. Although this is captioned as an "Information," the crimes, again, as I stated before are felonies.

Do you understand that Warner-Lambert by agreeing to waive indictment is giving up its right to require the government to present this case first to a grand jury to obtain the acquiescence of a grand jury in the Information?

MR. TEICHER: I do understand that, Your Honor.

THE COURT: Is it the advice of counsel that it is in the best interests of the corporation to proceed by waiver of indictment?

MR. TEICHER: Yes, Your Honor.

THE COURT: Does either counsel or Mr. Teicher know of any untoward threats or inducements that were given to Warner-Lambert to bring about the waiver of indictment in this case?

MR. TEICHER: No.

MR. ROUHANDEH: No, Your Honor.

THE COURT: Mr. Teicher, it is also your judgment that it is in the best interests of Warner-Lambert to proceed by way of Information?

MR. TEICHER: Yes.

THE COURT: All right. I find that the decision to proceed by waiver of indictment is a voluntary one and one made in the best interests of the corporate defendant. We will accept the waiver.

Mary, would you have Mr. Teicher sign the waiver.

THE CLERK: Yes.

(Pause in proceedings.)

THE COURT: All right. The waiver of indictment having been executed by Mr. Teicher, I will so witness the acceptance by signing and dating the waiver provided.

Now, Mr. Teicher, before I proceed with the Information, could you for the record -- because I think this may help clarify the factual basis for the Information to some degree -- could you explain the interrelationship between Parke-Davis, Warner-Lambert and Pfizer Corporation?

MR. TEICHER: I believe that Parke-Davis was an internal operating division of Warner-Lambert. And Warner-Lambert is currently, since June of 2000, a subsidiary of Pfizer Corporate.

THE COURT: Have you reviewed the Information

with counsel and has the Board of Directors reviewed the Information?

MR. TEICHER: Yes.

THE COURT: All right. Do you feel -- and, again, I am asking now to speak not only on your own behalf but on behalf of the Board of Directors.

Do you feel that you understand the two criminal charges contained in the Information?

MR. TEICHER: Yes.

THE COURT: Has counsel explained to you and to the Board of Directors the so-called, what a lawyer would call elements of these crimes, that is, the distinctive features of the crimes that the government would be required to prove beyond a reasonable doubt to obtain a conviction on both Counts 1 and 2?

MR. TEICHER: Yes.

THE COURT: All right. Let me simply summarize, and counsel can correct me if my summary is wrong.

Count 1 -- again, while a misdemeanor, it appears in the criminal code, because, as I said before, of the prior conviction, it has a felony consequence -- charges distribution of an unapproved drug. As framed this count would require proof of a prior conviction as I mentioned under the same operative statutes.

The sale of the drug with the tradename Neurontin was introduced in interstate commerce for unapproved uses and without prior FDA approval.

This crime, like Count 2, is a direct liability offense, that is, the government would not have to prove scienter but would have to prove the four elements I just described.

So too with Count 2 which alleges distribution of a misbranded drug. As framed this would require proof of a prior conviction under the same operative statutes, the sale of the drug under the tradename Neurontin in interstate commerce, and unapproved uses without adequate directions being provided to physicians and consumers for such uses.

These would be the elements that the government would have to prove.

Do I have them correctly stated, Counsel?

MR. KANWIT: Yes, you do, Your Honor.

MR. ROUHANDEH: Yes, Your Honor.

THE COURT: Do you understand that --

MR. TEICHER: Yes.

THE COURT: -- that is what would be involved?

All right. Now, let me ask Mr. Kanwit to explain -- and I realize that there is more art than perhaps science in this -- but explain the maximum penalties to the offense.

MR. KANWIT: Yes, Your Honor. The maximum penalties under 21 U.S.C., Section 333(a)(2) would be three years and a $10,000 fine. However, 18 U.S.C. provides for a $500,000 fine. And 18 U.S.C., Section 357(1)(d) provides for a fine of two times the pecuniary gain or loss. And the appropriate fine is the maximum of those.

Therefore, it's the United States' position with the agreement of the defendant that the maximum fine is two times the pecuniary gain.

THE COURT: Mr. Teicher, do you understand, at least as just as mortal human beings can calculate these things in the Sentencing Guidelines, that these are the maximum penalties of those offenses?

MR. TEICHER: Yes.

THE COURT: Now, I am going to ask the prosecutor to recite for the record the material terms of the plea agreement which was reached in this case.

And in doing this, Mr. Kanwit, you may also want to outline the terms of the civil settlement which I understand was a condition precedent to the government's recommendation of the disposition of the criminal matters.

MR. KANWIT: Thank you, Your Honor.

The plea agreement entered into between Warner-Lambert Company LLC and the United States provides that it is submitted to the Court under Criminal Rule

11(c)(1)(c).

And it provides that the defendant Warner-Lambert will plead guilty to two counts of violation of Title 21, United States Code, Sections 331(a), 331(d), 333(a), 352(f)(1) and 355(a).

Warner-Lambert in connection with its plea has agreed to waive any defenses, including statute of limitations defenses it has in connection with those crimes.

Further, Warner-Lambert and the United States have agreed that the United States Sentencing Guidelines will apply. And more specifically that pursuant to Section 8C2.4A2 and 18 U.S.C., Section 3571(d), the fine will be based on a calculation of pecuniary gain to Warner-Lambert, which pecuniary gain is one hundred fifty million dollars.

Further, the parties have agreed that the appropriate multiplier pursuant to the Sentencing Guidelines is 1.6. Although, as the Court is aware, the parties get to those -- get to that multiplier through somewhat different means. Nonetheless, the 1.6 is within the range that both parties reach. And the parties have agreed to the 1.6 multiplier under 8C2.6 of the Sentencing Guidelines.

And, therefore, the 1.6 multiplied by the pecuniary gain of one hundred fifty million results in an agreed upon criminal fine of two hundred and forty million.

There are additional provisions in the plea

agreement such as the mandatory special assessment of $800 to be paid to the Court by Warner-Lambert. And in addition the plea agreement contemplates the entry of Warner-Lambert into a civil settlement agreement and a Corporate Integrity Agreement.

The civil settlement agreement provides that Warner-Lambert will pay to the United States on behalf of False Claims Act and other damages pursuant to the Medicaid program and to the state a combined total of one hundred ninety million dollars and to state Consumer Protection divisions the amount of thirty-eight million dollars.

It is also contemplated as part of the Corporate Integrity Agreement that Warner-Lambert and its parent Pfizer will, and they have, in fact, at this point indeed entered into a Corporate Integrity Agreement which provides, among other things, for training of Warner-Lambert and Pfizer employees and auditing of those employees as regards marketing practices and related activity of the company's employees with regard to marketing, and very specifically potential off-label marketing.

There are over provisions of the plea agreement entered into by Warner-Lambert and the United States that relate to a breach of the plea agreement, that relate to the company's continued cooperation with the government, that relate to withdrawal of the plea agreement; but those are

the essential elements of the plea agreement between the United States.

THE COURT: Mr. Teicher, do you understand -- and I know that the plea agreement has been read carefully and acknowledged -- but do you understand that as this plea is offered, it is really offered to the Court because of the peculiar rule under which it was written as either a "take it or leave it proposition"? That is, either I approve the terms as counsel have agreed or Warner-Lambert is permitted to withdraw the plea, or the United States is also permitted to withdraw its consent to the plea.

Do you understand that?

MR. TEICHER: Yes, Your Honor.

THE COURT: I have an interesting question for counsel.

Is a corporation entitled to a jury trial in criminal cases?

MR. KANWIT: Your Honor, I actually don't know the answer to that. I always assumed that they are.

MR. ROUHANDEH: That's my understanding as well, Your Honor.

THE COURT: I don't think the Supreme Court has ever really answered the issue. The closest case I can find is Muniz vs. Hoffman where it seems to have been left as an open issue. A lot of academic writers take the

position that, in fact, because a corporation cannot be sentenced to imprisonment that the jury right does not apply, at least in a criminal context.

But let's be cautious. Let's assume that it does. And because we are being cautious, Mr. Teicher, do you understand that when Warner-Lambert pleads guilty, it gives up its right to have its case tried before a jury, or for that matter before a judge sitting without a jury?

MR. TEICHER: I do.

THE COURT: Have you served as a juror?

MR. TEICHER: No, I have never served as a juror.

THE COURT: All right. Let me simply explain that if the case were to go to trial in this court, a group of citizens randomly chosen from the eastern half of Massachusetts would be summoned to this courtroom. Ultimately twelve of them would be seated to serve as the jurors in the case.

During the course of this so-called impanelment process, your company and its attorneys would be permitted to object to any ten jurors for whatever reason it did not want them seated to hear the case. The government would object to any six that it did not want seated for any reason.

I would explain to the jury that they would have to

be unanimous as to whether Warner-Lambert, in fact, was guilty or not guilty of each of these offenses.

When I say that the company give ups its right to a jury trial, therefore, I mean not only does the company give up the right to have a jury make the ultimate factual determination as to whether the company is guilty or not guilty but also the right to participate in the selection of the very jury that would make that decision.

Do you understand that?

MR. TEICHER: Yes.

THE COURT: Do you understand that Warner-Lambert would be entitled to the assistance of counsel throughout the jury selection process and throughout the trial of the case?

MR. TEICHER: Yes, Your Honor.

THE COURT: Do you understand that I would instruct the jury that they must presume Warner-Lambert innocent unless or until the government succeeded in proving the company's guilt beyond a reasonable doubt?

MS. BEAMON: Yes.

THE COURT: Do you understand that I would also instruct the jury that the burden of proof rests with the government throughout the trial of the case, meaning that Warner-Lambert would have no duty to prove its innocence, to call witnesses, to produce evidence during the

trial?

Do you understand that?

MR. TEICHER: Yes.

THE COURT: Do you understand that the burden of proof in a criminal trial is proof beyond a reasonable doubt? That is the highest standard of proof known in our system of law.

MR. TEICHER: Yes.

THE COURT: Do you understand that Warner-Lambert by pleading guilty gives up the right to confront the witnesses against it? That means to have its lawyers ask questions of the government's witnesses.

MR. TEICHER: Yes, Your Honor.

THE COURT: And do you understand that the company gives up its right, if it should choose to do so, to present any defenses that its counsel thought were to its benefit during the course of the trial?

MR. TEICHER: Yes.

THE COURT: Do you also understand that the company, to the extent that it is a personality under the law, is in effect giving up its right I suppose to remain silent. I assume the Fifth Amendment applies to corporations?

Mr. Fiske, you would know the answer to that.

MR. FISKE: I am not sure, Your Honor. I

believe it does.

THE COURT: I think it would depend on the circumstances and the type of --

MR. FISKE: My colleague about thirty years ago David Kreiger (ph.) argued when he was U.S. Attorney that the Fifth Amendment did not apply to a corporation. And he lost that argument.

THE COURT: Well, that is good enough for me. We will, again, we will err on the side of caution.

You understand that the company may be giving up the right under the Fifth Amendment to refuse to produce any information or make any acknowledgements whatsoever with respect to these charges?

MR. TEICHER: I understand that, Your Honor.

THE COURT: All right. I am going to ask the prosecutor then to summarize the factual basis for the agreement in this case.

When he finishes, I have to ask if the company agrees with the material allegations that the government outlines.

MR. KANWIT: Thank you, Your Honor.

If this case were to go to trial, Your Honor, the United States would prove the following and more.

First, Warner-Lambert Company LLC was a corporation operating and existing under the laws of the State of

Delaware with its principal place of business in Morris Plains, New Jersey. Warner-Lambert's Parke-Davis Division was engaged in the development, manufacture, promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States. Those drugs were manufactured in Puerto Rico, from which they were shipped interstate to all fifty states and the District of Columbia.

The Federal Food, Drug and Cosmetic Act governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at 355(b), the Food, Drug and Cosmetic Act and its implementing regulations require that before a new drug may legally be distributed in interstate commerce, a sponsor of that drug product must submit a New Drug Application.

Further, the New Drug Application's sponsor must submit proposed labeling for the proposed intended uses for the drug which include, among other things, the conditions for the specific therapeutic use to which the drug is to be made.

The NDA, or the New Drug Application, must provide to the satisfaction of FDA, data generated in randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with

the proposed labeling.

The Food, Drug and Cosmetic Act at Section 355 further prohibits the introduction into interstate commerce of any new drug, unless such an approval of a New Drug Application is effective. No marketing or promotion of a drug may be made unless and until the application is approved and such marketing and promotion must be limited to the therapeutic use contained in the approval.

The Food, Drug and Cosmetic Act requires that before a manufacturer may label or promote a drug for use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA. Only upon approval of the new NDA or the amendment can the sponsor promote the drug for the new intended use.

Further, the Food, Drug and Cosmetic Act at all times relevant to this investigation provided that a drug was misbranded if the labeling did not contain adequate directions for use. Adequate directions for use cannot be written for medical indications or uses for which the drug could not be proven to be safe and effective.

The statute also prohibits distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

Turning to the specific facts of the Neurontin and

the Warner-Lambert situation. In or about 1993, Warner-Lambert submitted a New Drug Application for approval of a drug that was eventually called Neurontin, with the chemical name gabapentin.

Warner-Lambert sought to demonstrate the drug's safety and efficacy for, and sought approval for use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy.

On or about December 30, 1993, the FDA approved Neurontin for that specific use only. Neurontin was not approved for any use or condition other than what we have referred to in the Information as the approved use, this adult epilepsy I just referred to.

From at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis or ALS, spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy and migraine headaches, among other uses. We have referred to these collectively along with other uses as "Unapproved Uses."

Warner-Lambert did not file a new New Drug Application, or NDA, seeking FDA approval for any of these

unapproved uses during the time period addressed in the government's information.

Regarding the marketing strategy for Warner -- by Warner-Lambert for Neurontin, Warner-Lambert conducted evaluations of the market potential at various times for certain of the unapproved uses for Neurontin, including post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias and bipolar disorder.

In or about the fall of 1995 one regional unit, Warner-Lambert's Southeast Customer Business Unit, created a planning document regarding Neurontin, which included a page titled, "SECBU Right On The Mark with Neurontin and Pain" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

Further, certain of Warner-Lambert's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies and tactics for increasing sales of the unapproved uses of Neurontin. The marketing plans also budgeted for and funded these specific tactics.

From early 1995 on repeated occasions Warner-Lambert determined not to seek FDA approval for certain of the unapproved uses.

Specifically in or about April and May of 1995,

Warner-Lambert performed a marketing assessment of proposed psychiatric indications for Neurontin. In that marketing assessment Warner-Lambert forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: With and without FDA approval.

The company concluded that it would not seek approval to promote and sell Neurontin for those unapproved uses.

Further, in or about July of 1995 Warner-Lambert made an assessment of Neurontin's market potential for neuropathic pain. This was distributed within the company, including to a Vice President for Marketing. The assessment stated, "There is no intention to fully develop the indication at this point." Full development would have required the submission of a New Drug Application to FDA for approval.

One of the principal factors Warner-Lambert considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that Warner-Lambert had been developing.

The company expected that this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's approved use.

Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in Warner-Lambert's original NDA approval. If Warner-Lambert sought and obtained approval for any of the unapproved uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those unapproved uses. Warner-Lambert was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

Turning to the promotion of Neurontin for unapproved uses and specific tactics employed by Warner-Lambert. The government would prove at trial from in or about June of 1995 through in or about August 20, 1996, Warner-Lambert promoted the sale and use of Neurontin for certain conditions other than the approved use in Massachusetts and elsewhere.

The tactics employed included circulating a memorandum to a group including senior members of Warner-Lambert's Epilepsy Disease Team noting that data purchased from an outside vendor showed that the doctors had reported that the main message of certain sales pitches, known in the industry as "details" by sales representatives, given by ten of fifty Warner-Lambert sales representatives

for whom data was available in a two-month period was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

In addition, on about July 10, 1996 a Warner-Lambert sales representative met with a doctor in Monroe, Louisiana and detailed that doctor on Neurontin for the treatment of pain.

Also in 1996 another sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35 percent of all Neurontin use is non-seizure. The same document entitled "Neurontin Can Do/Can't Do," stated that sales representatives could do lunch programs on Neurontin and pain.

Turning to the tactic of using medical liaisons. Warner-Lambert employed persons called "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department.

On a specific occasion in or about June of 1996, a Warner-Lambert sales representative requested that a medical liaison with the company make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

Prior to the meeting the sales representative and the medical liaison selected the topic that would be presented to the medical society. Among the topics actually presented were the use of Neurontin for unapproved uses. And that was done in front of -- there were doctors and in front of the sales representative.

After the presentation a Warner-Lambert medical director who was aware of the event praised it as "another great example of use of the medical liaisons" and an area business manager who oversaw sales representatives called it an "outstanding utilization of...one of the medical affairs liaisons."

Further, in or about May of 1996 a Warner-Lambert medical director who oversaw medical liaisons in the Northeast Customer Business Unit, which was a regional sales unit for the company, sent a voice mail message to the Medical Liaisons in the Northeast CBU in which he stated, "What we'd like you to do is, anytime you're called out just make sure that your main focus out of what you're doing is on Neurontin... When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything we can talk about, that's what we want to do."

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should

promote Neurontin for unapproved uses and thereafter promoted Neurontin for neuropathic pain, which is an unapproved use.

Turning to the tactic of use of consultant meetings and advisory Boards in promoting Neurontin. Specifically Warner-Lambert organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida held on April 19 to 21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to the unapproved uses of Neurontin.

Warner-Lambert invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, Warner-Lambert paid for the accommodations and meals for the invited doctors and their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between $1,500 and $2,000.

Among the presentations made to the physicians in attendance was one relating to unapproved uses entitled, "Reduction of Pain Symptoms During Treatment with Gabapentin."

In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

Additional presentations made at the Jupiter Beach conference also addressed unapproved uses.

Following the Jupiter Beach conference Warner-Lambert circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. The company told its employees that, "The meeting was a great success and the participants were delivered a hard-hitting message about Neurontin."

Warner-Lambert also distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

In addition, from August 1st through the 5th, 1996, Warner-Lambert organized and held an advisory board meeting in Atlanta, Georgia in connection with the 1996 Summer Olympics. Warner-Lambert expressly instructed several of the physician speakers to address some of the unapproved uses of Neurontin at that meeting.

The meeting was hosted for the doctors at the Chateau Elan Winery and Resort in Atlanta, Georgia, and all expenses were paid for eighteen consultants and their spouses to attend the Olympics, including tickets to the

closing ceremonies. The company had already had numerous opportunities to consult with these doctors and, in fact, many of them had spoken on Warner-Lambert's behalf at prior meetings.

In addition, certain of the physician speakers promoted Neurontin for unapproved uses in their presentations at this meeting.

Turning to the off-label promotion of Neurontin through teleconferences.

Warner-Lambert organized teleconferences as part of its effort to increase off-label sales of Neurontin.

Specifically in or about January of 1996 a Warner-Lambert vice president of the Southeast Customer Business Unit sent a memorandum to Warner-Lambert sales representatives listing certain goals, including, "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric Market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

On or about March 1st, 1996, Warner-Lambert sponsored such a teleconference moderated by a Warner-Lambert employee with a pain specialist as a speaker on Neurontin. Neurontin was promoted for the treatment of pain to doctors participating in that teleconference.

Further, on or about March 28, 1996, a

Warner-Lambert Medical Director in the Northeast Customer -- I'm sorry -- the Northcentral Customer Business Unit sent a memorandum to Warner-Lambert Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy and other non-epilepsy use data. Monotherapy is use of Neurontin alone rather than in conjunction with another epilepsy medication and it was an off-label use.

In or about May 1996 a Warner-Lambert Medical Director held such a teleconference in the Northcentral Customer Business Unit entitled, "Neurontin, A Clinical Update" which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

Your Honor, those are the essential facts that if the government went to trial it would expect to prove. In addition, there are facts contained in the Sentencing Memo submitted by the government which the government believes are relevant conduct.

Clearly the expectation of the United States is that were we to go to trial, we would prove more than what is in the Information. But what is in the Information are the essential facts that we would prove that would be sufficient to sustain a conviction on Counts 1 and 2.

Count 1, as the Court has noted, being distribution

of an unapproved new drug, and Count 2, the distribution of a misbranded drug by reason of inadequate directions for use.

THE COURT: All right.

Mr. Teicher, I think much of this would be unsurprising to you because it is contained in the Sentencing Memorandum the government filed, which I am sure that you have seen.

And I do recognize that in its own Sentencing Memorandum, the company does, without arguing the point of guilt, nonetheless, it points to some mitigating factors. For example, the fact that to the company's knowledge no individual has been harmed by any of the activities that the government has recited.

But I am going to focus now on what the prosecutor related as the facts of the case as the government sees them.

Does Warner-Lambert agree that that recitation is factually accurate and the responsibilities that the prosecutor pointed to which lead to the suggestion or actually an inference of a felony nature of guilt in this matter are accurately stated?

MR. TEICHER: Warner-Lambert acknowledges the facts stated by the U.S. Attorney to the extent as set forth in the Information, Your Honor.

THE COURT: Is the company pleading guilty voluntarily and willingly?

MR. TEICHER: Yes.

THE COURT: Has any coercion of a physical nature, other than obviously the threat of prosecution, been brought to bear to induce the company to plead guilty?

MR. TEICHER: No, Your Honor.

THE COURT: Have any promises of a secret nature, that is, any promise other than those that have been disclosed to the Court in the plea agreement and the release been made to induce a plea agreement?

MS. BEAMON: No.

THE COURT: Again, apart from the threat of prosecution, have any untoward threats been made to induce the guilty plea?

MR. TEICHER: No.

THE COURT: Is Warner-Lambert satisfied with the representation that its attorneys have provided and does it feel that it has had sufficient time to elicit the advice of its attorneys, discuss any possible defenses and the consequences of entering a guilty plea in this case?

MR. TEICHER: Yes, Your Honor.

THE COURT: Is Warner-Lambert satisfied that its attorneys have represented the corporate interests at all times?

MR. TEICHER: Yes.

THE COURT: Do counsel for Warner-Lambert see any reason why the plea should not be accepted in this case?

MR. ROUHANDEH: No, Your Honor.

THE COURT: Do counsel have any other areas that you wish me to inquire into?

MR. KANWIT: No, Your Honor.

THE COURT: Okay.

MR. ROUHANDEH: No, Your Honor.

THE COURT: None.

All right. Mr. Teicher, your ordeal is almost over. If you would step back to counsel table.

(Pause in proceedings.)

THE COURT: All right. I find that the pleas tendered on behalf of Warner-Lambert are voluntary. They have been tendered after a full discussion with counsel of whatever legal rights that Warner-Lambert may have and is waiving as a result of the pleas.

And after consideration by the corporate Board of Directors, it is in the company's best interests in this matter to find that there is a sufficient basis in the facts submitted by the government, particularly those that are outlined in the Information, the accuracy of which Warner-Lambert acknowledges, to warrant a finding of guilt on each of the offenses beyond a reasonable doubt.

I further find that given the magnitude of the fine that is recommended, the associated civil settlement, the fact that the plea agreement and the associated release do not compromise any private right or any potential criminal liability of individual defendants, or any other criminal conduct, corporate or otherwise, that lies outside the scope of the agreement, I find that the agreement and the proposed disposition are in the public's interest.

I would, therefore, accept the pleas and direct the clerk at this time to enter the pleas into the record.

THE CLERK: Mr. Teicher, would you stand, please.

Mr. Teicher, Count 1 of the Information filed by the United States Attorney charges Warner-Lambert Company with distribution of unapproved new drug, beginning as early as in or about April of 1995, and continuing thereafter until at least in or about August 20 of 1996, in the District of Massachusetts, and elsewhere, all in violation of Title 21, United States Code, Sections 331(d), 333(a)(2) and 355(a).

How does Warner-Lambert Company plead to Count 1 of this Information?

MR. TEICHER: Warner-Lambert Company pleads guilty.

THE CLERK: And Count 2 of the Information

filed by the United States Attorney charges Warner-Lambert Company with distribution of a misbranded drug, beginning as early as April of 1995, and continuing thereafter until at least in or about August 20 of 1996, in the District of Massachusetts and elsewhere, all in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(f)(1).

How does Warner-Lambert Company plead to Count 2 of the information?

MR. TEICHER: Warner-Lambert Company pleads guilty.

THE CLERK: Thank you, sir. Please be seated.

THE COURT: I have a motion before the Court filed by the United States asking that the Court waive the Presentence Report and proceed immediately to sentencing in this matter.

Is that the case, Mr. Kanwit?

MR. KANWIT: That is, Your Honor, provided that we, of course, want to be sure that the Court has had an adequate opportunity to look into this matter and feels comfortable with it.

THE COURT: The reason I was hesitant when you all came in two or three weeks ago and asked me to conduct the hearing then is that I would not have felt comfortable at that point. I didn't realize that the interest was

running quite on the meter the way it was or I might have hurried my own review.

But, nonetheless, I think it is in the interests of the court and the interests of the public that the judge feel informed and comfortable about the matter in this case.

And I am, as I said, particularly having read the terms of the release associated with the plea agreement and those provisions as I indicated of the agreement that did not purport to compromise any rights except those immediately at stake in this proceeding.

I am comfortable not only with the plea but with the proposed disposition.

Mr. Teicher, I gather it is also the desire of Warner-Lambert to proceed immediately to sentencing?

MR. TEICHER: Yes, it is, Your Honor.

THE COURT: You understand that the company would ordinarily have the right to have a Presentence Report prepared by the Probation Department for further advice and information to the Court?

MR. TEICHER: Yes, Your Honor.

THE COURT: You are willing to waive that right of the company?

MR. TEICHER: Yes.

THE COURT: Mr. Kanwit, what is the government's recommendation?

I know what it is but for the record could you state the government's recommendation.

MR. KANWIT: Your Honor, it's the United State's recommendation that Warner-Lambert Company LLC have imposed upon it a criminal fine of two hundred forty million dollars; a special assessment of $800; that restitution be waived in light of the civil settlement agreement; and no period of probation be imposed in light of the Corporate Integrity Agreement.

THE COURT: Mr. Rouhandeh, I gather Warner-Lambert concurs in the recommended disposition?

MR. ROUHANDEH: Yes, Your Honor.

THE COURT: Mr. Teicher, if you would stand, please.

Mr. Teicher, pursuant to the Sentencing Reform Act of 1984 and the associated Sentencing Guidelines, it is the judgment of the Court that the defendant Warner-Lambert Company LLC be fined the sum of two hundred and forty million dollars, the fine to be paid within fourteen days of the date of this sentencing.

I further order that the company pay a special assessment of $800 which should be due immediately.

In light of the civil agreement entered into previously, the Court will waive any restitution in this matter.

Any technical imperfection in the sentence as dictated?

MR. KANWIT: Not that the government is aware of, Your Honor. Could I have one moment?

THE COURT: Yes.

(Pause in proceedings.)

MR. KANWIT: Thank you, Your Honor. Nothing from the government.

MR. ROUHANDEH: No, Your Honor.

THE COURT: All right. The sentence will then be imposed as it was orally dictated by the Court.

Unless counsel have anything further, we will be adjourned on this matter.

MR. ROUHANDEH: Yes, Your Honor. Just one point just for the record. And that is that Mr. Teicher had no involvement whatsoever in any of the charged or investigated conduct.

I wanted the record to be clear on that.

THE COURT: I assumed that that is why he was so chosen to be the representative today.

(Laughter.)

THE COURT: Okay.

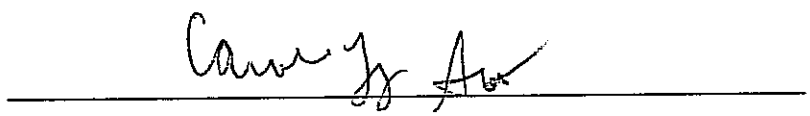
All right. With that additional statement for the record, we will be adjourned.

THE CLERK: All rise. Court is in recess.

(WHEREUPON, the proceedings were recessed at 3:30 p.m.)

C E R T I F I C A T E

I, Carol Lynn Scott, Official Court Reporter for the United States District Court for the District of Massachusetts, do hereby certify that the foregoing pages are a true and accurate transcription of my shorthand notes taken in the aforementioned matter to the best of my skill and ability.



CAROL LYNN SCOTT
Official Court Reporter
John J. Moakley Courthouse
1 Courthouse Way, Suite 7204
Boston, Massachusetts 02210
(617) 330-1377

PEGGY W. LANE
CIRCUIT COURT CLERK
111 Court Avenue Room 201
NEWPORT, TENNESSEE 37821

(423) 623-6124

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
220 West Depot Street, Suite 200
Greeneville, Tennessee 37743

(423) 639-3105
www.tned.uscourts.gov

PATRICIA L. McNUTT
Clerk of the Court

JOHN L. MEDEARIS
Chief Deputy Clerk

September 16, 2004

Gordon Ball
Bass & Scott
550 Main Avenue
750 NationsBank Center
Knoxville, TN 37902

RE: 2-04-CV-337 BAUDA VL SUTTON V. PFIZER, INC., ET AL

Dear Attorney(s):

The above-styled case was removed to our court from the Circuit Court for Cocke County. Please note the new case no. 2:04-cv-337

All pleadings should be mailed to us with that case number on them. The other defendants need to send copies of any documents they have filed in state court and send all further pleadings here.

Thank you very much for your cooperation.

Sincerely,

s/Kim Ottinger
Deputy Clerk

xc: Shelly L. Wilson
Joel T. Galanter

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
GREENEVILLE

BAUDA VAUDA LEE SUTTON	)	
	)	
V.	)	NO. 2:04-CV-337
	)	
PFIZER, INC., ET AL	)	

O R D E R

This matter is before the United States Magistrate Judge, pursuant to the standing order of the Court, with respect to the defendant's Motion for Enlargement of Time [Doc. 5], and the Joint Motion to Stay [Doc. 6].

The Joint Motion to Stay requests that all deadlines and required disclosures and any other proceedings before this Court be stayed. The Judicial Panel on Multidistrict Litigation ["MDL"] has entered an order consolidating and transferring dozens of similar cases across the county to the District of Massachusetts. Defendants herein have filed a Notice of Related Action in that case and both parties expect that an order will issue from the MDL transferring this case to Massachusetts. The Motion to Stay is therefore GRANTED, and the stay shall remain in effect for sixty (60) days after transfer of this action to the MDL Court, or until as otherwise ordered by the MDL Court. The Motion for Extension of Time is DENIED in that it is no longer relevant.

SO ORDERED:

s/ Dennis H. Inman
United States Magistrate Judge

DOCKET NO. 1629

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE NEURONTIN MARKETING AND SALES PRACTICES LITIGATION

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO-1) 2:04-cv-337

On October 26, 2004, the Panel transferred 23 civil actions to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. With the consent of that court, all such actions have been assigned to the Honorable Patti B. Saris.

It appears that the actions on this conditional transfer order involve questions of fact which are common to the actions previously transferred to the District of Massachusetts and assigned to Judge Saris.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the District of Massachusetts for the reasons stated in the order of October 26, 2004, ___F. Supp. 2d___ (J.P.M.L. 2004), and, with the consent of that court, assigned to the Honorable Patti B. Saris.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the District of Massachusetts. The transmittal of this order to said Clerk shall be stayed fifteen (15) days from the entry thereof and if any party files a notice of opposition with the Clerk of the Panel within this fifteen (15) day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Michael J. Beck
Clerk of the Panel

SCHEDULE CTO-1 - TAG ALONG ACTIONS
DOCKET NO. 1629
IN RE NEURONTIN MARKETING AND SALES PRACTICES LITIGATION

DISTRICT	DIV.	C.A.#	
ALABAMA MIDDLE			
ALM	2	04-711	Alabama Forest Products Industry Workmen's Compensation Self-Insurer's Fund v. Pfizer, Inc., et al.
ALABAMA SOUTHERN			
ALS	1	04-463	Nancy Coleman, et al. v. Pfizer, Inc., et al.
FLORIDA SOUTHERN			
FLS	1	04-22228	Ana Medero, et al. v. Pfizer, Inc., et al.
ILLINOIS NORTHERN			
ILN	1	04-4467	Allied Services Division Welfare Fund v. Pfizer, Inc., et al.
LOUISIANA EASTERN			
LAE	2	04-1735	Linda Rizzo v. Pfizer, Inc.
LAE	2	04-2087	Tracey Lynn Robichaux, et al. v. Pfizer, Inc.
LAE	2	04-2509	Louisiana Health Service Indemnity Co. v. Pfizer, Inc., et al.
MISSOURI EASTERN			
~~MOE~~	~~4~~	~~04-982~~	~~Elizabeth Judy v. Pfizer, Inc., et al.~~ Vacated 12/1/04
MISSISSIPPI NORTHERN			
~~MSN~~	~~2~~	~~04-255~~	~~Mary Cooper, et al. v. Pfizer, Inc.~~ Opposed 12/1/04
~~MSN~~	~~4~~	~~04-275~~	~~Leroy Anderson, et al. v. Pfizer, Inc., et al.~~ Opposed 12/1/04
NEW JERSEY			
NJ	2	04-4236	Steven Kail, et al. v. Pfizer, Inc., et al.
NJ	2	04-4497	International Union of Operating Engineers Local No. 68 Welfare Fund v. Pfizer, Inc., et al.
NJ	2	04-4593	Alaska Electrical Pension Fund v. Pfizer, Inc., et al.
OKLAHOMA EASTERN			
OKE	6	04-375	Jerry Hollaway, et al. v. Pfizer, Inc., et al.
TENNESSEE EASTERN			
TNE	2	04-337	Bauda V.L. Sutton v. Pfizer, Inc., et al.
TEXAS EASTERN			
~~TXE~~	~~2~~	~~04-309~~	~~Linda Barker v. Pfizer, Inc., et al.~~ Opposed 12/7/04

Jeffrey B. Aaronson
Bell, Boyd & Lloyd
3 First National Plaza
70 West Madison Street,
Suite 3200
Chicago, IL 60602-4207

Daniel F. Attridge
Kirkland & Ellis
Suite 1200
655 Fifteenth St.,N.W.
Washington, DC 20005

Gary L. Azorsky
Berger & Montague, PC
1622 Locust Street
Philadelphia, PA 19103

Anita B. Bapooji
Testa, Hurwitz & Thibeault, LLP
125 High Street
Oliver Tower
Boston, MA 02110

Jason E. Baranski
Morgan Lewis & Bockius, LLP
1701 Market Street
Philadelphia, PA 19103-2921
Assigned: 06/25/2002

Steven F. Barley
Hogan & Hartson, LLP
111 South Calvert Street
Baltimore, MD 21202

Rebecca Bedwell-Coll
Mascone, Emblidge & Quadra
180 Montgomery Street
San Francisco, CA 94104

Mark A. Berman
Gibbons, Del Deo, Dolan, Griffinger & Vecchione, P.C.
One Riverfront Plaza
Newark, NJ 01702-5497

Steve W. Berman
Hagens & Berman
1301 5th Avenue
Suite 2900
Seattle, WA 98101-1090

David J. Bershad
Milberg Weiss Bershad Hynes & Lerach LLP
One Pennsylvania Plaza
49th Floor
New York, NY 10119

Aimee E. Bierman
Kirkpatrick & Lockhart, LLP
75 State Street
Boston, MA 02109-1808

Jack B. Blumenfeld
Morris, Nichols, Arsht, & Tunnell
1201 North Market Street
Wilmington, DE 19899-1347

Thomas L. Boeder
Perkins Coie
1201 Third Avenue, 40th Floor
Seattle, WA 98101-3099

Anthony Bolognese
Bolognese & Associates
Suite 650
One Penn Center
1617 JFK Blvd.
Philadelphia, PA 19103

James J. Breen
Breen Law firm
3562 Old Milton Parkway
Alpharetta, GA 30005

Jill Lori Brenner
Donnelly, Conroy & Gelhaar, LLP
One Beacon Street
33rd Floor
Boston, MA 02108

Douglas S. Brooks
Kelly, Libby & Hoopes, PC
175 Federal Street
Boston, MA 02110

Nicole Y. Brumsted
Lieff Cabraser Heimann & Bernstein, LLP
175 Federal Street, 7th Floor
Boston, MA 02110

Michael M. Buchman
Milbert, Weiss, Bershad, Hynes & Lerach, LLP
One Pennsylvania Plaza
NewYork, NY 10119-0165

James C. Burling
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

David J. Burman
Perkins Coie
1201 Third Avenue, 40th Floor
Seattle, WA 98101-3099

Evan Dean Buxner
676 North Michigan Avenue
Suite 3110
Chicago, IL 60611-0003

James P. Carroll, Jr.
Kirby Mclnerney & Squire
830 3rd Avenue
10th Floor
New York, NY 10022

Tod S. Cashin
Buchanan Ingersoll, PC
700 Alexander Road
Suite 300
Princeton, NJ 08540

Ronald L. Castle
Arent,Fox,
Kintner,Plotkin,Plotkin &
Kahn, LLC
1050 Conneticut Ave., N.W.
Washington, DC 20036-6188

William F. Cavanaugh, Jr.
Patterson, Belknap, Webb &
Tyler LLP
1133 Avenue of the Americas
New York, NY 10036-6710

David J. Cerveny
Proskaver Rose LLP
One International Place
14th Floor
Boston, MA 02110

Eric P. Christofferson
Ropes & Gray, LLP
One International Place
Boston, MA 02110

Joanne M. Cicala
Kirby Mclnerncy & Squire
830 3rd Ave.
10th Floor
New York, NY 10022

Daniel J. Cloherty
Dwyer & Collora LLP
600 Atlantice Avenue
12th Floor
Boston, MA 02210

Jonathan D Cohen
Greenberg Traurig, LLP
One International Place
Boston, MA 02110

Jeremy P. Cole
Jones Day
Suite 3500
77 West Wacker Drive
Chicago, IL 60601-1692

Christopher R. Cook
Jones Day
51 Louisiana Avenue, N.W.
Washington, DC 20001

Robert C. Cook
Jones Day
51 Louisiana Avenue, NW
Washington, DC 20001

Michael R. Costa
Greenberg Traurig, LLP
One International Place
Boston, MA 02110

Paul J. Coval
Vorys, Sater, Seymour and
Pease, LLP
52 East Gay Street
Columbus, OH 43215

William M. Cowan
Mintz, Levin, Cohn, Ferris,
Glovsky & Popeo, PC
One Financial Center
Boston, MA 02111

Florence A Crisp
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

Jonathan W. Cuneo
Cuneo Law Group
317 Massachusetts Avenue,
N.E.
Washington, DC 20002

Christopher J. Cunio
Cooley, Manion, & Jones,
LLP
21 Custom House Street
Boston, MA 02110

Joseph Danis
The David Danis Law Firm,
P.C.
8235 Forsyth Blvd.
Suite 1100
St. Loius, MO 63105

William A. Davis
Mintz, Levin, Cohn, Ferris,
Glovsky & Popeo, PC
701 Pennsylvania Avenue,
N.W.
Suite 200
Washington, DC 20004

Michael DeMarco
Kirkpatrick & Lockhart, LLP
75 State Street
Boston, MA 02109

Merle M. Delancey, Jr.
Dickstein Shapiro Morin &
Oshinsky LLP
2101 LStreetN.W.
Washington, DC 20037

Jeanne E. Demers
Kirkpatrick & Lockhart, LLP
75 State Street
Boston, MA 02109

John C. Dodds
Morgan Lewis & Boskius,
LLP
1701 Market Street
Philadelphia, PA 19103-2921

Lloyd Donders
Kirby Mclnerney & Squire
830 3rd Avenue
10th Floor
New York, NY 10022

Alan J. Droste
Pillsbury Winthrop
650 Town Center Dr
7th Floor
Costa Mesa, CA 92626-7122

James J Duffy
Davis Polk & Wardwell
450 Lexington Ave
New York, NY 10017

Dennis M. Duggan, Jr.
Nixon Peabody, LLP
101 Federal Street
Boston, MA 02110

Kimberly A. Dunne
Sidley Austin Brown & Wood
555 West 5th Street
Suite 4000
Los Angeles, CA 90013-1010

Thomas E. Dwyer, Jr.
Dwyer & Collora, LLP
Suite 1200
600 Atlantic Avenue
Boston, MA 02210

Marc H. Edelson
Hoffman & Edelson
45 West Court Street
Doylestown, PA 18901

Mitchell Edwards
Morgan Lewis & Bockius, LLP
1701 Market Street
Philadelphia, PA 191 03-2921

Steven M. Edwards
Hogan & Hartson, LLP
875 Third Avenue
Suite 2600
New York, NY 10012

Robert G. Eisler
Lieff Cabraser Heirnann & Bernstein, LLP
780 Third Avenue
48th Floor
New York, NY 10017-2024

Bruce E. Falby
Piper Rudnick LLP
One International Place, 21st Floor
100 Oliver Street
Boston, MA 02110-2600

Douglas Farquhar
Hyman, Phelps & McNamara, P.C.
Suite 1200
700 13th Street, N.W.
Washington, DC 20005

Eric B. Fastiff
Leiff, Cabraser, Heimann & Bernstein, LLP
Embarcadero Center West
275 Battery Street
30th Floor
San Francisco, CA 94111-3339

Joseph B.G. Fay
Morgan Lewis & Bockius, LLP
1701 Market Street
Philadelphia, PA 19103-2921

Anastasia M. Fernands
Goodwin Procter LLP
Exchange Place
53 State Place
Boston, MA 02109

Elizabeth S. Finberg
Sonnenschein, Nath & Rosenthal, LLP
1301 K Street, NW
East Tower
Suite 600
Washington, DC 20005

Kathryn C. Finnerty
58th Floor, US Steel Tower
600 Grant Street
Pittsburgh, PA 15219

Matthew A. Fischer
Sedgwick, Detert, Moran & Arnold
One Embarcadero Center
16th Floor
San Francisco, CA 94111

Michael J. Flannery
The David Danis Law Firm, P.C.
8235 Forsyth Blvd.
Suite 1100
St. Louis, MO 63105-7700

Lucy Fowler
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02210-2600

Brian V. Frankel
Department of Justice
California Bureau of Med i-Cal Fraud and Elder Abuse
1455 Frazee Road
Suite 315
San Diego, CA 92108

Todd G. Friedland
Pillsbury Winthrop
650 Town Center Dr
7th Floor
Costa Mesa, CA 92626-7122

Jeffrey S. Friedman
Silverman & McDonald
1010 North Bancroft Parkway
Suite 22
Wilmington, DE 19805

Todd S. Garber
Lowey Dannenberg Bemporad & Selinger, P.C.
The Gateway
One North Lexington Ave
White Plains, NY 10601

Scott Garland
United States Department of Justice
Suite 600
1301 New York Avenue
Washington, DC 20530

Martin F. Gaynor, III
Cooley, Manion, Jones LLP
21 Custom House
Boston, MA 02110

Peter E. Gelhaar
Donnelly, Conroy & Gelhaar, LLP
One Beacon Street
33rd Floor
Boston, MA 02108

Evan Georgopoulos
Greenberg Traurig, LLP
One International Place
Boston, MA 02110

David C. Giardina
Sidley Austin Brown & Wood
Bank One Plaza
10 South Dearborn Street
Chicago, IL 60603

Alison C. Gilbert
Hogan & Hartson, LLP
875 Third Avenue
Suite 2600
New York, NY 10012

Arthur F. Golden
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

David F. Graham
Sidley Austin Brown & Wood
Bank One Plaza
10 South Dearborn Street
Chicago, IL 60603

Karen F. Green
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

Gary R. Greenberg
Greenberg Traurig, LLP
One International Place
Third Floor
Boston, MA 02110

Daniel E. Gustafson
Hems Mills & Olson, P.L.C.
3550 IDS Center
80 South Eighth Street
Minneapolis, MN 55402

Erik Haas
Patterson, Belknap, Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036-6710

Sonnenschein, Nath & Rosenthal, LLP
Suite 600, East Tower
1301 K Street NW
Washington, DC 20005

Blake M. Harper
Hulett Harper
550 West C Street
Suite 1770
San Diego, CA 92101

Kimberley D. Harris
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

Elizabeth Fegan Hartweg
Kenneth A. Wexler & Associates
1 North La Salle
Suite 2000
Chicago, IL 60602

Reed Elliott Harvey
Pillsbury Winthrop
650 Town Center Dr
7th Floor
Costa Mesa, CA 92626-7122

Kirke M. Hasson
Pillsbury Winthrop LLP
50 Freemont Street
P.O. Box 7880
San Francisco, CA 94120

Joseph Ernest Haviland
Dwyer & Collora, LLP
Federal Reserve Building
600 Atlantic Avenue
12th Fl.
Boston, MA 02210

James Vincent Hayes
Williams & Connolly, LLP
725 Twelfth Street N.W.
Washington, DC 20005

George B. Henderson
United States Attorneys Office
1 Courthouse Way
Suite 9200
Boston, MA 02210

James P. Rouhandeh
Davis, Polk & Wardwell
450 Lexington Avenue
New York, New York
10017

Colleen M. Hennessey
Peabody & Arnold LLP
30 Rowes Wharf
Boston, MA 02110

Mary Ellen Hennessy
Katten Muchin & Zavis
525 W. Monroe, Suite 1600
Chicago, IL 60661-3693

Frederick G. Herold
Dechert LLP
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103-2793

Nicola R. Heskett
Shook, Hardy & Bacon LLP
2555 Grand Blvd
Kansas City, MO 64108

Robert J. Higgins
Dickstein, Shapiro & Morin
2101 L Street, N.W.
Washington, DC 20037

Aaron D. Hovan
Kirby Mclnerney & Squire LLP
830 3rd Avenue
10th Floor
New York, NY 10022

Joel T. Galanter
Stokes Bartholomew Evans & Petree, P.A.
424 Church Street, Suite2800
Nashville, TN 37219